

Exhibit U

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Page 1

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON &)
JOHNSON TALCUM POWDER)
PRODUCTS MARKETING)
SALES PRACTICES AND) MDL 16-2738
PRODUCT LIABILITY) (FLW)(LHG)
LITIGATION)
_____)
THIS DOCUMENT)
PERTAINS TO ALL CASES)

WEDNESDAY, DECEMBER 19, 2018

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Videotaped deposition of Laura
Plunkett, Ph.D., DABT, held at the Four
Seasons Hotel, 999 North 2nd Street, St.
Louis, Missouri, commencing at 9:12 a.m., on
the above date, before Carrie A. Campbell,
Registered Diplomate Reporter, Certified
Realtime Reporter, Illinois, California &
Texas Certified Shorthand Reporter, Missouri
& Kansas Certified Court Reporter.

- - -

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Page 2	Page 4
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Page 3	Page 5
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Page 6	Page 8
<p>1 VIDEOGRAPHER: We are now on 2 the record. 3 My name is Jacob Arndt. I'm a 4 videographer for Golkow Litigation 5 Services. 6 Today's date is December 19, 7 2018, and the time is 9:12 a.m. 8 This deposition is being held 9 in St. Louis, Missouri, In Re: Johnson 10 & Johnson Products Marketing Sales 11 Practices, for the United States 12 District Court for the District of 13 New Jersey. 14 The deponent is Dr. Laura 15 Plunkett. 16 Will counsel please identify 17 themselves? 18 MR. MEADOWS: Ted Meadows for 19 plaintiffs. 20 MS. PARFITT: Michelle Parfitt 21 for the plaintiffs. 22 MR. BEATTIE: Ryan Beattie for 23 plaintiffs. 24 MR. TISI: Chris Tisi for 25 plaintiffs.</p>	<p>1 DIRECT EXAMINATION 2 QUESTIONS BY MS. BRANSCOME: 3 Q. All right. Good morning, 4 Dr. Plunkett. I introduced myself right 5 before we started, but my name is Kimberly 6 Branscome, and I am here on behalf of Johnson 7 & Johnson. 8 Is it your understanding today 9 that you are giving your deposition for the 10 purpose of a Daubert analysis in the MDL 11 related to Johnson's baby powder? 12 A. That's my understanding, yes. 13 (Plunkett Exhibit 1 marked for 14 identification.) 15 QUESTIONS BY MS. BRANSCOME: 16 Q. I want to start by handing you 17 what I will mark as Plunkett Deposition 18 Exhibit 1. 19 Do you recognize the document 20 that I just handed you? 21 A. Yes. 22 Q. Okay. Have you seen this 23 document before? 24 A. Yes. 25 Q. All right. When was this</p>
Page 7	Page 9
<p>1 MR. GOLOMB: Richard Golomb for 2 plaintiffs. 3 MR. LOCKE: Tom Locke for the 4 Personal Care Products Council. 5 MS. TINSLEY: Caroline Tinsley 6 for PTI Union, LLC, and PTI Royston, 7 LLC. 8 MR. SULLIVAN: Ryan Sullivan 9 for Imerys. 10 MS. BOCKUS: Jane Bockus for 11 Imerys. 12 MR. SMITH: William Smith for 13 Johnson & Johnson. 14 MS. BRANSCOME: Kimberly 15 Branscome for Johnson & Johnson. 16 VIDEOGRAPHER: Thank you. 17 The court reporter is Carrie 18 Campbell and will now swear in the 19 witness. 20 LAURA PLUNKETT, Ph.D., DABT, 21 of lawful age, having been first duly sworn 22 to tell the truth, the whole truth and 23 nothing but the truth, deposes and says on 24 behalf of the Defendant Johnson & Johnson, as 25 follows:</p>	<p>1 document provided to you? 2 A. Either earlier this -- this 3 week or late last week. I don't recall if it 4 was Friday or Monday. 5 Q. Okay. For the purposes of the 6 record, could you just identify what the 7 document is that I just handed you as 8 Plunkett Deposition Exhibit Number 1? 9 A. It's a notice of oral and 10 videotaped deposition for myself, dated -- I 11 don't see the date, but probably on the very 12 last -- do you need that or just -- is that 13 enough of an identification? 14 Q. That's all right. 15 Now, contained within the 16 deposition notice there is a reference to a 17 request for materials that are identified in 18 more detail in Schedule A. 19 Do you see that? 20 A. Yes. 21 Q. Have you reviewed Schedule A? 22 A. Yes. 23 Q. Did you bring any documents 24 with you in response to the request in 25 Schedule A?</p>

3 (Pages 6 to 9)

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Page 10	Page 12
<p>1 A. The only thing that I believe 2 that I had to bring that had not already been 3 provided was additional billing since the 4 time of my last deposition. 5 Q. Okay. And is it my 6 understanding that the documentation related 7 to additional billing that you have done 8 since your prior deposition was produced 9 yesterday at the deposition in the Forrest 10 case? 11 A. That's correct. 12 Q. All right. And the information 13 contained in the documents produced at the 14 Forrest deposition yesterday, do those 15 contain an up-to-date record of the billing 16 that you have submitted for your work in 17 connection with the litigation against 18 Johnson & Johnson? 19 A. Yes, with the understanding 20 that I haven't submitted a bill for December 21 yet. 22 Q. Okay. How much time have you 23 spent working in connection with your 24 opinions in the case against Johnson & 25 Johnson related to its baby powder in the</p>	<p>1 but I'll bill separately for the time I spent 2 yesterday right before the deposition and 3 then at the deposition, so... 4 Q. What did you do to prepare for 5 your deposition today? 6 A. I reviewed my reports, the 7 three reports that I filed in the litigation. 8 I had a meeting with attorneys on Monday, and 9 then we had a short meeting yesterday evening 10 because some attorneys arrived that were not 11 here on Monday. 12 And essentially went through 13 some of the documents that -- went through 14 some of the documents that I had cited in the 15 report in certain paragraphs, just to refresh 16 my memory of what they were. So if you want 17 me to tell you which paragraphs, I can do 18 that. 19 Q. I will in just a moment. Okay. 20 A. Want me to repeat that? I'm 21 sorry. 22 Q. That's all right. 23 Dr. Plunkett, you referenced 24 the fact that you reviewed specific 25 paragraphs of your expert reports in</p>
Page 11	Page 13
<p>1 month of December? 2 A. So I'm -- on all the cases that 3 I am involved in that are pending, not just 4 this deposition? 5 Q. I'll ask first all cases and 6 then we'll narrow it to the deposition. 7 A. So in all -- 8 Q. I mean to the MDL, I'm sorry. 9 A. Okay. So in all cases this 10 month, probably eight hours so far, maybe 11 ten. 12 Q. Does that include the time that 13 you've spent attending deposition? 14 A. No, that's not including 15 yesterday's deposition time. I apologize. I 16 forgot about that. 17 Q. And how much of the eight to 18 ten hours that you have spent this month 19 working on these cases against Johnson & 20 Johnson, setting aside the time you spent in 21 deposition yesterday, relate to the MDL 22 specifically? 23 A. So it will probably be 24 billed -- it will be one bill for the 25 preparation time because the prep overlapped,</p>	<p>1 preparation for today's deposition. 2 Could you identify those 3 paragraphs for me? 4 And it's helpful to you, we can 5 go ahead and mark your three expert reports, 6 if you're referring to all three. 7 A. I'm going to refer just to the 8 MDL report because that's what we're here to 9 talk about. I mean, if you want to talk 10 about what I did to get ready for yesterday 11 separately or -- 12 MR. MEADOWS: Might be helpful 13 to go ahead and mark them. 14 MS. BRANSCOME: Why don't we go 15 ahead and just mark the three reports, 16 and then we can walk through. 17 (Plunkett Exhibits 2, 3 and 4 18 marked for identification.) 19 QUESTIONS BY MS. BRANSCOME: 20 Q. So, Dr. Plunkett, do you have a 21 copy of your three reports in front of you? 22 A. Yes, I do. 23 Q. Do those contain any markings, 24 highlightings or flags? 25 A. No, they don't.</p>

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Page 14	Page 16
<p>1 Q. Okay. Do you mind if we mark 2 your copies as the official records? 3 A. No, that's fine. 4 Q. So we will mark -- well, let's 5 do this in chronological order. So I am 6 marking as Plunkett Deposition Exhibit 7 Number 2 the expert report of Dr. Plunkett 8 dated October 5, 2016. 9 Could you confirm, 10 Dr. Plunkett, that that's what I marked as 11 Deposition Exhibit Number 2? 12 A. Yes, it is. 13 Q. And then we will mark as 14 Deposition Exhibit Number 3 supplemental 15 expert report of Dr. Laura Plunkett dated 16 August 29, 2018. 17 Dr. Plunkett, could you confirm 18 that I marked that as Exhibit Number 3? 19 A. Yes, that's correct. 20 Q. And then Exhibit Number 4, we 21 will mark the expert report dated 22 November 16, 2018, by Dr. Plunkett that was 23 produced in the MDL. 24 Could you confirm that I marked 25 that as Deposition Exhibit Number 4?</p>	<p>1 are also cited in paragraph 39 as well, some 2 of those same ones that are... 3 And then in Section 5 of my 4 report where I'm talking about exposure, I 5 looked again at Parmley and Woodruff. I 6 looked again at Vetner and Iturrulde and Egli 7 and Newton last night. 8 And the only other thing I 9 looked at is not cited in this report because 10 it came out after the report was filed, and 11 that was -- and I did bring a copy of that. 12 That was the risk assessment that was done in 13 Canada. Some people refer to it as -- by the 14 first author's last name, Taher, T-a-h-e-r. 15 And I may be pronouncing that wrong, but... 16 (Plunkett Exhibit 5 marked for 17 identification.) 18 QUESTIONS BY MS. BRANSCOME: 19 Q. All right. And I see that you 20 brought a copy of that document with you. 21 Just for the purposes of the record, let's 22 mark that as Plunkett Deposition Exhibit 23 Number 5. 24 Are there any markings, 25 highlightings or notations on that document?</p>
Page 15	Page 17
<p>1 A. Yes, that's correct. 2 Q. All right. And so now back to 3 the question of you referenced the fact that 4 you looked at specific paragraphs of your 5 expert report in preparation for today's 6 deposition. If you could, using Deposition 7 Exhibit Number 4, identify which paragraphs 8 you looked at specifically in preparation for 9 the deposition. 10 A. So it wasn't the paragraphs. 11 There were certain documents in paragraphs, 12 so that's what I was referring to, so... 13 So starting in paragraph 38 14 where I'm talking about sort of the timeline 15 of information about human health hazards and 16 talc dust. So I just went back and refreshed 17 on a few of the older papers. 18 I looked again at the patent 19 documents that are cited in the first bullet. 20 I looked again at a paper by 21 Eberl, 1948, which is in the last bullet. 22 The patent documents are also there as well. 23 And that -- so that would be 24 all I pulled in that paragraph. 25 I believe that those documents</p>	<p>1 A. No, there's not. 2 And then the other document I 3 looked at that was not cited in the report, 4 there is a printout from the government of 5 Canada website that talks about some 6 statements on talc, and so I printed that out 7 as well. This was published at the same time 8 that the risk assessment was published. 9 (Plunkett Exhibit 6 marked for 10 identification.) 11 QUESTIONS BY MS. BRANSCOME: 12 Q. All right. We'll mark that for 13 purposes of the record as Plunkett Deposition 14 Exhibit Number 6. We might come back to 15 those documents. 16 So returning briefly to the 17 deposition notice and the requests in 18 Schedule A, the billing information you 19 produced yesterday and then we just discussed 20 additional information with respect to that, 21 are there any other documents that you have 22 in your possession that are responsive to 23 requests identified in Schedule A that have 24 not been produced? 25 A. I don't believe so, no.</p>

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Page 18	Page 20
<p>1 Everything -- I do believe that there were 2 some objections filed to this, so there's 3 some things that I did not provide based on 4 that. 5 Some of the things I don't 6 have, too. I think you asked for -- maybe 7 you didn't ask for that. Usually people ask 8 for copies of old depositions, and I don't 9 keep those. And maybe you didn't ask for 10 that, but that's usually a request. 11 Let me see. 12 Q. Okay. Now, you mentioned that 13 you met with attorneys on Monday. And who 14 was present at that meeting? 15 A. So on Monday it was 16 Mr. Meadows, sitting here. Ms. Tucker, 17 Mr. Beattie, were at the meeting on Monday. 18 Q. All right. And how long did 19 that meeting last? 20 A. Probably six hours, I guess, 21 six hours with them, and then I also did some 22 other work on my own, but... 23 Q. Okay. And then you mentioned 24 that you had another meeting last night. 25 Who was present at that</p>	<p>1 Q. All right. And then you 2 produced a supplemental report earlier this 3 year, on August 29, 2018, and that's been 4 marked as Deposition Exhibit Number 3, 5 correct? 6 A. Yes. 7 Q. When did you begin work on the 8 supplemental report that you produced at the 9 end of August in 2018? 10 A. I want to say -- let's see. I 11 want to say sometime in the summer. Maybe as 12 early as May, but I believe May -- May, June 13 time frame of 2018. 14 My billing would reflect that, 15 so, again, we can pull my billing. And I 16 would have called it preparation of the 17 supplemental report in my billing. 18 Q. Okay. Why did you choose to 19 draft a supplemental expert report? 20 A. So over the time I had worked 21 on different trials here in St. Louis 22 particularly, additional documents that were 23 not cited in my original report became 24 reliance materials based on their 25 presentation at trial. So there were enough</p>
Page 19	Page 21
<p>1 meeting? 2 A. So that was probably about an 3 hour, and that would have been Mr. Tisi -- or 4 maybe two hours. Mr. Tisi joined us 5 yesterday afternoon. And Mr. Golomb, too, 6 I'm sorry. 7 Q. All right. Okay. Now, looking 8 at the three reports that you have produced 9 in the litigation involving Johnson's baby 10 powder, I wanted to get an understanding of 11 how those three reports relate to one 12 another. 13 So you have the first report 14 that you produced that was dated October 5, 15 2016. I believe that was originally produced 16 in the Uhl case; is that correct? 17 A. I'm not sure the name of the 18 first case, but it was in the -- some of the 19 St. Louis cases, yes. 20 Q. All right. And when did you 21 begin work on that report? 22 A. You'd have to look at my 23 billing record, which I know was an exhibit 24 to yesterday's deposition. I believe they 25 started in 2015.</p>	<p>1 of those that I thought it was important to 2 add to the original report with additional 3 documents that I had reviewed over time. 4 Since October of 2016 through, 5 let's say, the summer of 2018, there were a 6 variety of additional documents that I had -- 7 I had seen. 8 It was also my understanding 9 that during that time period Johnson & 10 Johnson had provided additional documents 11 that weren't provided or available to me in 12 2016, so additional discovery that was now 13 available to look at. So some of this is a 14 matter of additional evidence that wasn't 15 available when I wrote my initial -- my 16 initial report. 17 Q. All right. Now when you say 18 the additional documents became reliance 19 materials in trial, what do you mean by that? 20 A. So additional documents that we 21 refer to in trial that I use to support 22 opinions that weren't necessarily 23 specifically cited within the body of my 24 report or described within the body of my 25 report. They were likely on my larger</p>

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Page 22	Page 24
<p>1 reliance list, but they weren't things that 2 were cited. 3 In other words, if you look at 4 my original report in -- when I say the body, 5 the paragraphs. I always put a reference 6 list and then I'll have Bates numbers. So 7 during trial, things that were from my larger 8 reliance list that weren't specifically 9 discussed in my report became support for 10 different opinions that -- based on questions 11 at trial. 12 Q. Okay. When you say these were 13 documents that "we" refer to at trial, you're 14 referring to yourself and attorneys 15 representing the plaintiffs? 16 A. Yes, that's correct. 17 Q. Okay. And understanding that 18 the purpose of today's deposition is focused 19 specifically on the MDL, then you produced a 20 report specific to the MDL on November 16, 21 2018, that we've marked as Exhibit 4, 22 correct? 23 A. Yes. 24 Q. When did you begin work on the 25 report that you produced specifically in the</p>	<p>1 ask who the -- who was involved in the 2 drafting of the report that was produced in 3 the MDL? 4 MR. MEADOWS: Hold on just one 5 second. 6 Ask the question one more time. 7 I want to make sure we're not 8 venturing into attorney work product 9 realm here. 10 QUESTIONS BY MS. BRANSCOME: 11 Q. Dr. Plunkett, do you consider 12 the report that you have issued in the MDL 13 which is identified as Exhibit 4 to be 14 attorney work product? 15 MR. MEADOWS: Objection. Don't 16 answer that. That calls for a legal 17 conclusion, and at this point I'm 18 going to instruct you not to answer 19 questions about how the report came 20 into be. 21 MS. BRANSCOME: Are you 22 instructing her to refuse to answer 23 any questions that involve the 24 development of her expert report? 25 MR. MEADOWS: I'm instructing</p>
Page 23	Page 25
<p>1 MDL? 2 A. Sometime right after -- I would 3 say early fall of 2018, sometime after 4 this -- the supplemental report was filed. 5 Probably right after that. 6 Q. Okay. So is it fair to say 7 that you began work on your MDL report after 8 completing the supplemental expert report 9 that has been marked as Exhibit 3? 10 A. Yes, that's correct. 11 Q. Okay. Who was involved in the 12 drafting of the report that's been identified 13 as Exhibit 4? 14 MR. MEADOWS: Objection. Hang 15 on a second. 16 Are you asking about 17 communications between attorneys and 18 Dr. Plunkett? 19 QUESTIONS BY MS. BRANSCOME: 20 Q. Dr. Plunkett, none of the 21 questions I will ask you here today are 22 intended to elicit information that's 23 protected by the attorney-client privilege. 24 So setting that aside, anything 25 that you understand to be privileged, I can</p>	<p>1 her not to answer your last question. 2 QUESTIONS BY MS. BRANSCOME: 3 Q. Are you following your 4 attorney's instructions, Dr. Plunkett? 5 A. Yes. 6 MS. BRANSCOME: At this point I 7 would like to go off the record, 8 please. 9 VIDEOGRAPHER: Okay. We are 10 going off the record at 9:30 a.m. 11 (Off the record at 9:30 a.m.) 12 VIDEOGRAPHER: We are back on 13 the record at 9:32 a.m. 14 QUESTIONS BY MS. BRANSCOME: 15 Q. Dr. Plunkett, other than 16 attorneys, if attorneys were involved -- I am 17 not asking questions about that -- were there 18 any individuals who assisted you in preparing 19 the report that has been marked as Exhibit 4? 20 A. There was no one that actually 21 assisted in writing the report. I do -- when 22 I did my literature searches, I had my 23 husband help me retrieve articles that I 24 identified for retrieval, but certainly there 25 was no -- he doesn't participate in the</p>

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Page 26	Page 28
<p>1 actual review of articles or in drafting of</p> <p>2 the report. That's all my work.</p> <p>3 Q. Okay. And when you say that</p> <p>4 your husband retrieved articles, was this</p> <p>5 simply -- what information did you provide</p> <p>6 him in order to enable him to retrieve a</p> <p>7 particular article?</p> <p>8 A. So we use a service in Houston</p> <p>9 called Loansome Doc, which is affiliated with</p> <p>10 our local medical library system and also</p> <p>11 with the National Library of medicine and NIH</p> <p>12 libraries. So I give him an online search</p> <p>13 that I put into a clipboard. He takes that,</p> <p>14 makes the request or retrieves -- some of</p> <p>15 them will be free, and so he'll actually go</p> <p>16 to the websites for the -- and then put them</p> <p>17 into a folder for me.</p> <p>18 So he does that physical part</p> <p>19 of it through the computer, but he doesn't --</p> <p>20 he doesn't do the searches or decide which</p> <p>21 ones to retrieve. I do that.</p> <p>22 Q. Okay. Did you have any</p> <p>23 discussions with your husband about the</p> <p>24 substantive content of the report that's</p> <p>25 identified as Exhibit 4?</p>	<p>1 been marked as Exhibits 2, 3 and 4 to each</p> <p>2 other, what is your -- what is your position</p> <p>3 with respect to opinions that you have stated</p> <p>4 or language you have used in Exhibits 2 and 3</p> <p>5 that may not appear in Exhibit 4?</p> <p>6 A. I don't think I understand what</p> <p>7 your -- what you mean by my position. Are</p> <p>8 you asking --</p> <p>9 MS. PARFITT: And I'll object</p> <p>10 to that question.</p> <p>11 THE WITNESS: Are you asking me</p> <p>12 to describe -- I mean, I could</p> <p>13 describe for you the overlap. I mean,</p> <p>14 there's not complete overlap. Is that</p> <p>15 what you're asking me or --</p> <p>16 QUESTIONS BY MS. BRANSCOME:</p> <p>17 Q. I am. Why don't you take a</p> <p>18 shot at it and then I may narrow my question,</p> <p>19 but I'm just trying to understand how the</p> <p>20 reports relate to one another.</p> <p>21 MR. MEADOWS: Objection.</p> <p>22 THE WITNESS: So they relate to</p> <p>23 each other, I would say, based on</p> <p>24 timing first, because obviously the</p> <p>25 first report was two years ago, and</p>
Page 27	Page 29
<p>1 A. No.</p> <p>2 Q. Does he do any evaluation --</p> <p>3 for example, if you were to provide him a</p> <p>4 search and it generates multiple documents by</p> <p>5 a given author, does he identify additional</p> <p>6 articles that you might want to consider?</p> <p>7 A. Only -- he has done that, but</p> <p>8 only with the streams of letters to the</p> <p>9 editor. So I ask him always if I'm pulling</p> <p>10 an article. Happens a lot at the New England</p> <p>11 Journal of Medicine or some of the other</p> <p>12 medical journals where there's pretty active</p> <p>13 letter to the editor correspondence that</p> <p>14 happens.</p> <p>15 So I always say to him, "If</p> <p>16 there's any citation to this through the</p> <p>17 letter to the editor comments, would you</p> <p>18 please retrieve those," and so he will do</p> <p>19 that search to look for that.</p> <p>20 Q. Okay.</p> <p>21 A. And I'm not sure that that</p> <p>22 happened in any of these articles, but I'm</p> <p>23 talking my general process that we use.</p> <p>24 Q. Okay. In terms of the</p> <p>25 relationship of the three reports that have</p>	<p>1 then many more documents. So that's</p> <p>2 how the 1 and 2 relate -- or Exhibit 2</p> <p>3 and 3 relate to each other.</p> <p>4 In the MDL litigation, I was</p> <p>5 asked to address very specific topics</p> <p>6 and things because there's a -- it's a</p> <p>7 different -- I don't know all of them,</p> <p>8 but there's a different set of experts</p> <p>9 that work in different litigations.</p> <p>10 So my role in the MDL, I</p> <p>11 believe, is set out based on this</p> <p>12 report, whereas in the original</p> <p>13 reports I may have had -- I did have a</p> <p>14 broader role in some of those cases.</p> <p>15 QUESTIONS BY MS. BRANSCOME:</p> <p>16 Q. Okay. Can you describe for me</p> <p>17 your understanding of your role in the MDL?</p> <p>18 A. It's my understanding that I</p> <p>19 have been asked to provide opinions related</p> <p>20 to the -- generally the toxicology of talcum</p> <p>21 powder products, including all the individual</p> <p>22 constituents that make up that product; to</p> <p>23 look historically back in time about what was</p> <p>24 known and when about the toxic effects of</p> <p>25 talc and different constituents within talc.</p>

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Page 30	Page 32
<p>1 And that was sort of the -- that's been --</p> <p>2 I consider that sort of the meat of what I've</p> <p>3 been asked to do.</p> <p>4 But separate from that, another</p> <p>5 part important part of my testimony or things</p> <p>6 I was asked to provide was an overview of the</p> <p>7 regulatory process for cosmetics and then the</p> <p>8 information that accumulated scientifically,</p> <p>9 how that related to what a company is</p> <p>10 required to do under the regulations in order</p> <p>11 to provide consumers with appropriate</p> <p>12 information about the safety of the product.</p> <p>13 So kind of the regulatory opinions, I guess</p> <p>14 you want to call it, that area.</p> <p>15 I have sections on that, and I</p> <p>16 think you can see that by the different</p> <p>17 sections in my report where I set out</p> <p>18 different general topics.</p> <p>19 And then I was also asked to</p> <p>20 address some of the issues related to how the</p> <p>21 information on the safety of talc has been</p> <p>22 disseminated publicly and also based on my</p> <p>23 review of different internal company</p> <p>24 documents, both from Johnson & Johnson -- or</p> <p>25 from Johnson & Johnson, Imerys, as well as</p>	<p>1 the companies had, in fact, influenced the</p> <p>2 regulators or PCPC?</p> <p>3 MR. MEADOWS: Objection.</p> <p>4 THE WITNESS: Not in my -- not</p> <p>5 when I first started this process. So</p> <p>6 that is -- those opinions actually go</p> <p>7 back into my original report. So</p> <p>8 that's not something, I don't believe,</p> <p>9 that was not covered in my original</p> <p>10 report or even in my supplemental</p> <p>11 report. I just have different -- some</p> <p>12 additional documents that I have</p> <p>13 reviewed.</p> <p>14 QUESTIONS BY MS. BRANSCOME:</p> <p>15 Q. Okay.</p> <p>16 A. And this is something when I</p> <p>17 first evaluated the case and first started</p> <p>18 looking at the documents, those are opinions</p> <p>19 that I had formed based on my review.</p> <p>20 Certainly by the time I drafted</p> <p>21 the MDL report, I think if you listened to</p> <p>22 my -- read my trial testimony, you understand</p> <p>23 I had those opinions at the time I started</p> <p>24 writing this report.</p> <p>25 Q. Now, what I'd like to</p>
Page 31	Page 33
<p>1 the PCPC, which is the Personal Care Products</p> <p>2 Council, formerly known as the CTFA, to look</p> <p>3 at those interactions and how those companies</p> <p>4 set about to influence the process around the</p> <p>5 safety assessment of talc over the years. So</p> <p>6 different activities that happened with</p> <p>7 respect to the ISRTP meetings in the '90s,</p> <p>8 with respect to the NTP process at different</p> <p>9 points in time.</p> <p>10 The CIR process, I think I</p> <p>11 cover, and I also talk a little bit about</p> <p>12 IARC, I believe, as well.</p> <p>13 So the interactions of the</p> <p>14 industry with the science and then how that</p> <p>15 science ends up getting described within --</p> <p>16 either to regulators or to bodies that are</p> <p>17 reviewing the science related to the</p> <p>18 products.</p> <p>19 Q. You mentioned as one of the</p> <p>20 categories that you were asked to opine about</p> <p>21 in the MDL that you were looking to set about</p> <p>22 the influence that companies may have exerted</p> <p>23 over the regulatory process or PCPC.</p> <p>24 When you began that analysis,</p> <p>25 did you start with the predicate belief that</p>	<p>1 understand next is, are there -- of the</p> <p>2 topics that you just identified that you</p> <p>3 understand that you're offering opinions</p> <p>4 about in the MDL, which, if any, of those</p> <p>5 topics are in your view new as compared to</p> <p>6 the opinions that you have offered that are</p> <p>7 contained in Exhibits 2 and 3?</p> <p>8 MS. PARFITT: Objection.</p> <p>9 THE WITNESS: So I don't think</p> <p>10 any of the MDL opinions are new.</p> <p>11 QUESTIONS BY MS. BRANSCOME:</p> <p>12 Q. Okay.</p> <p>13 A. I think that they may have --</p> <p>14 they may -- they may cite to additional</p> <p>15 documents that haven't been cited to in the</p> <p>16 first two reports, but I believe there's a</p> <p>17 significant overlap even on the documents</p> <p>18 that are cited.</p> <p>19 Q. And you mentioned that your</p> <p>20 role in the MDL is more narrow than the role</p> <p>21 you've served in other cases.</p> <p>22 What topics have you opined</p> <p>23 about in other cases that you are not</p> <p>24 intending to opine about in the MDL?</p> <p>25 A. So I am not doing general</p>

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Page 34	Page 36
<p>1 causation in the MDL, although I am indeed</p> <p>2 providing opinions on certain aspects of the</p> <p>3 cause and effect relationship such as -- you</p> <p>4 know, I talk about biologic plausibility,</p> <p>5 underlying knowledge about different</p> <p>6 toxicities of the compounds over time, but</p> <p>7 I'm not doing a full causation analysis in my</p> <p>8 MDL report, and hopefully you see that when</p> <p>9 you read the report.</p> <p>10 Q. So as you sit here today,</p> <p>11 Dr. Plunkett, you are not intending to offer</p> <p>12 the opinion in the MDL that Johnson's baby</p> <p>13 powder causes ovarian cancer; is that</p> <p>14 correct?</p> <p>15 A. Not in those words. I think if</p> <p>16 you read my report, I talk about the</p> <p>17 fact that Johnson -- it's my opinion that</p> <p>18 Johnson's baby powder increases the risk of</p> <p>19 cancer -- ovarian cancer, which is a</p> <p>20 different assessment than the way you stated</p> <p>21 it.</p> <p>22 Q. All right. And it is -- as you</p> <p>23 sit here today, Dr. Plunkett, it is your</p> <p>24 understanding that you are not being offered</p> <p>25 to give a, as you termed it, a general</p>	<p>1 principles of, first, is there a hazard, is</p> <p>2 the first step. Is there a hazard that would</p> <p>3 be relevant to human health.</p> <p>4 Then looking at the data and</p> <p>5 determining whether that -- that body of data</p> <p>6 allows you to either quantify risk in some</p> <p>7 way or to qualitatively shows you that</p> <p>8 there's a change in risk based on exposure to</p> <p>9 the product.</p> <p>10 So your statement may be as</p> <p>11 simple as there's an increased risk, or you</p> <p>12 can take data in a risk assessment and do a</p> <p>13 quantification such as in a -- a cancer risk</p> <p>14 assessment based on an animal data set. You</p> <p>15 might actually calculate a cancer potency</p> <p>16 factor, for example. Those kinds of things.</p> <p>17 That's another application of risk</p> <p>18 assessment. Same basic process but focusing</p> <p>19 just, for example, on one study.</p> <p>20 My human health risk assessment</p> <p>21 or safety assessment, like the causation</p> <p>22 analysis, does look across all kinds of data,</p> <p>23 but my goal was not to analyze the data under</p> <p>24 the Hill considerations, which is what I</p> <p>25 would typically do, in order to go through</p>
Page 35	Page 37
<p>1 causation opinion in the MDL, correct?</p> <p>2 A. That's my understanding, yes.</p> <p>3 Q. Now, you mentioned that the</p> <p>4 analysis as to whether a substance increases</p> <p>5 the risk of a particular outcome is different</p> <p>6 than a causation analysis.</p> <p>7 Can you explain to me what you</p> <p>8 meant by that?</p> <p>9 A. So I discussed this yesterday</p> <p>10 in my deposition. There's -- there's a</p> <p>11 process called risk assessment. Sometime --</p> <p>12 in the area of consumer products you can also</p> <p>13 refer to it as safety assessment. And then</p> <p>14 there's the process of what I call general</p> <p>15 causation analysis, or full causation</p> <p>16 analysis.</p> <p>17 So even though the types of</p> <p>18 information that are considered may overlap</p> <p>19 between those two, the outcome or the</p> <p>20 statements or the -- the way you go about</p> <p>21 assessing the information is a bit different.</p> <p>22 Q. Explain to me how they're</p> <p>23 different.</p> <p>24 A. So in a risk assessment, the</p> <p>25 process starts with setting out some basic</p>	<p>1 the process of making that final opinion that</p> <p>2 indeed baby powder -- exposure to baby powder</p> <p>3 through genital application is a cause of</p> <p>4 ovarian cancer in women. That's -- to me,</p> <p>5 that's a different way to go about thinking</p> <p>6 about the question that you have to answer.</p> <p>7 And also the -- some of the</p> <p>8 data that you evaluate is evaluated a bit</p> <p>9 differently. So, for example, in my</p> <p>10 increase -- in my issue of increased risk, I</p> <p>11 use the epidemiology as supporting evidence,</p> <p>12 but I'm really focused on -- on -- more on</p> <p>13 the underlying sort of the biologic</p> <p>14 information that we have that identifies</p> <p>15 hazard and risk. So looking at the animal</p> <p>16 data, the exposure potential for the product,</p> <p>17 and then using that along with what we know</p> <p>18 with the human experience to characterize</p> <p>19 risk.</p> <p>20 Q. Is there a different level of</p> <p>21 certainty required to render a causation</p> <p>22 opinion than to render an opinion that</p> <p>23 there's an increased risk?</p> <p>24 A. I don't know that I'd describe</p> <p>25 it quite that way but -- because to me it's a</p>

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Page 38	Page 40
<p>1 different process. I certainly have to be 2 just as certain about what I say about risk 3 when I do a risk assessment as I do about -- 4 as I do when I'm doing a causation analysis. 5 I don't -- maybe you mean 6 something else, so maybe you can -- I mean, 7 I -- I certainly use the same basic standards 8 in my mind, how I weigh evidence to do the 9 different processes, but I go about them in a 10 little bit different way when I do a risk 11 assessment versus -- versus a causation 12 analysis. 13 Q. In your view, does the strength 14 of the evidence have to be greater in order 15 to determine that an agent causes a disease, 16 for example, than it does simply to say that 17 an agent increases the risk of a particular 18 outcome? 19 MR. MEADOWS: Objection. 20 THE WITNESS: I don't think 21 I've ever thought about it that way. 22 I would say to you that strength -- 23 the strength of the association is a 24 consideration under Hill that you 25 apply the epidemiology data mainly, so</p>	<p>1 statistical test you would apply, or 2 what are you asking? 3 QUESTIONS BY MS. BRANSCOME: 4 Q. So understanding that for the 5 most part if you're looking at statistical 6 significance, you're looking whether the 7 confidence interval crosses 1. 8 Are you following? 9 A. Yes, I know that, yeah. 10 Q. All right. And so when you're 11 evaluating, though, whether a particular 12 substance, in this case Johnson's baby 13 powder, increases the risk of an outcome, 14 again, in this case ovarian cancer, would it 15 be sufficient for you if that increase was 16 .01 percent, for example? 17 MR. MEADOWS: Objection. 18 THE WITNESS: That doesn't make 19 sense to me, an increase of .01 20 percent, but maybe I can answer it 21 this way for you based on what you've 22 laid out there. 23 Certainly when I do a risk 24 assessment and I make it -- if I'm 25 going to make the conclusion that I</p>
Page 39	Page 41
<p>1 that is a different consideration 2 under causation than you do -- as you 3 would do it in a risk assessment. 4 But the strength of the 5 evidence, it's still a judgment based 6 on your experience and training as far 7 as whether or not there is enough 8 information to be able to say that you 9 believe that there is -- enough 10 information to say that the risk is 11 increased based on that exposure and 12 those conditions and whatever the 13 toxicity profile of that compound is. 14 QUESTIONS BY MS. BRANSCOME: 15 Q. Okay. We'll get into this more 16 a little bit later, but when you say that a 17 risk is increased, is there a threshold level 18 of increase that you need to see in order to 19 render an opinion in a court of law that an 20 agent increases the risk of a particular 21 outcome? 22 MR. MEADOWS: Objection. 23 THE WITNESS: So I need you to 24 define what you mean by threshold. 25 Are you asking me a specific</p>	<p>1 believe that it's my opinion to a 2 reasonable degree of scientific 3 certainty that exposure to baby powder 4 in women increases the risk of cancer, 5 I'm having to rely on -- I do rely on 6 data that allows me to draw 7 conclusions because either there's a 8 statistical significant finding found 9 or the -- there's a consistency among 10 the pattern of the data that shows 11 there's information that fits together 12 consistently. And maybe -- you want 13 me to explain what I mean by that? 14 No? 15 Whereas I think what you're 16 asking is when an epidemiologist 17 applies -- looks at a body of -- in a 18 causation analysis looks at a body -- 19 and I do this, too -- looks at a body 20 of epidemiological studies and you 21 weight the studies, obviously you're 22 weighting the studies differently 23 based on whether they have shown 24 statistical significance or not, 25 right?</p>

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<p style="text-align: right;">Page 42</p> <p>1 And it isn't that it's a one to 2 one. If you have one positive and one 3 negative, that isn't how you may 4 decide to finally weight that 5 evidence, but certainly you have to 6 consider whether or not what was seen 7 or reported is showing you something 8 reliable -- or you can make a 9 statement reliably about whether or 10 not that finding was biologically 11 significant. And biologically 12 significant would typically be linked 13 to a finding that has statistical 14 significance in an epi study unless 15 the study was not designed to be able 16 to answer the question properly. 17 So -- and I've discussed that a 18 little bit yesterday with Mr. Smith on 19 the issue of power to detect. So 20 that's something you do consider in 21 epi. 22 But, yes, statistical 23 significance certainly goes into your 24 weight of the evidence there. 25</p>	<p style="text-align: right;">Page 44</p> <p>1 company evaluating compliance with FDA 2 regulations with respect to cosmetics? 3 A. Yes. 4 Q. Okay. What is your experience 5 with respect to that? 6 A. So that's -- one of the clients 7 that I currently work for where I am asked to 8 provide input on advertising, promotion and 9 labeling of some of the products and then 10 also some of the ingredients that are being 11 promoted for use to -- to produce cosmetic 12 products. So it's the idea of providing that 13 advice over my understanding of the 14 regulations what can be said and can't be 15 said about certain ingredients. 16 This company is involved in 17 making both ingredients but also some 18 finished products now based on -- it's a 19 large company that owns a lot of little 20 subsidiaries. 21 Q. My question, though, 22 Dr. Plunkett, was, have you ever been in a 23 decision-making position for a company 24 evaluating compliance with FDA regulations 25 with respect to cosmetics?</p>
<p style="text-align: right;">Page 43</p> <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Okay. You talked about you're 3 intending to offer an opinion with respect to 4 what a company is required to do under the 5 regulations; is that correct? 6 A. Yes. 7 Q. Okay. What regulations are you 8 specifically referring to? 9 A. So cosmetic regulations that 10 exist within -- so it's the entire process as 11 I describe how cosmetic -- what -- are 12 cosmetics subject to regulation by FDA? Yes. 13 What are the types of things that companies 14 have to do before they're marketed, what does 15 the company have to do once the product is on 16 the market, those kinds of things. 17 Q. Have you ever worked directly 18 for any regulatory agency? 19 A. No, I have not. 20 Q. And suffice it to say you have 21 never been in a decision-making position 22 within a regulatory agency, correct? 23 A. That's correct, I have not. 24 Q. Have you ever been in a 25 decision-making position with respect to a</p>	<p style="text-align: right;">Page 45</p> <p>1 MS. PARFITT: Objection. Asked 2 and answered. 3 THE WITNESS: So that's what 4 I'm saying. They're relying on my 5 input to make a decision on what will 6 go in the materials. 7 QUESTIONS BY MS. BRANSCOME: 8 Q. Do you have decision-making 9 authority within that company or, as you 10 described it, are you providing advice and 11 input? 12 A. I'm providing advice, but the 13 things I'm advising on are the things that 14 happened. So in other words, they don't have 15 anybody in the company that understands the 16 process of what they can say. So I -- I 17 advise them that you need to remove this 18 language or that this is more appropriate 19 language. They make those changes, and then 20 that is what is done. 21 So I agree, I'm not an employee 22 of that company. I am a consultant working 23 with the company, but it is a little 24 different than some of the work that I do 25 where I -- what I -- the advice that I'm</p>

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Page 46	Page 48
<p>1 giving is actually something that I know</p> <p>2 actually happened. Sometimes you give advice</p> <p>3 to companies, but it doesn't -- we have no</p> <p>4 idea whether the company actually follows our</p> <p>5 advice.</p> <p>6 Q. My question is slightly</p> <p>7 different, Dr. Plunkett.</p> <p>8 If you were to give advice to</p> <p>9 the company that you've referenced as having</p> <p>10 experience with cosmetic regulation</p> <p>11 compliance that that company chose not to</p> <p>12 follow, that company has the ability to</p> <p>13 ignore your advice, correct?</p> <p>14 A. Yes, I would imagine that they</p> <p>15 could do that.</p> <p>16 Q. Okay. Have you ever drafted</p> <p>17 regulations that relate to cosmetics?</p> <p>18 A. Actually drafted a regulation?</p> <p>19 No, I have not.</p> <p>20 Q. All right. You reference in</p> <p>21 your report language out of 21 CFR 740.1, and</p> <p>22 specifically -- you reference it in a few</p> <p>23 places. And I can direct you specifically to</p> <p>24 paragraph 22 in Exhibit 4.</p> <p>25 A. Yes. I'm there.</p>	<p>1 A. So it's -- first off, you would</p> <p>2 use the common English language definition.</p> <p>3 I don't believe that those -- I haven't seen</p> <p>4 a definition separate within the regulations.</p> <p>5 Sometimes there will be.</p> <p>6 So based on that and my</p> <p>7 experience and the looking into what others</p> <p>8 have described about this, this is the idea</p> <p>9 of considering how the product is used, is</p> <p>10 one of the -- one of the concerns that you</p> <p>11 have, and whether or not the -- based on how</p> <p>12 the product is used and how the product is</p> <p>13 being sold, that in order to prevent a health</p> <p>14 hazard, a warning hazard -- a warning</p> <p>15 statement would be needed.</p> <p>16 Q. Can you cite to me any language</p> <p>17 within the regulation or even supporting</p> <p>18 documentation, a comment, something of that</p> <p>19 nature, that would define "whenever necessary</p> <p>20 or appropriate" with respect to how the</p> <p>21 product is used?</p> <p>22 MS. PARFITT: Objection.</p> <p>23 THE WITNESS: I don't think I</p> <p>24 understand your question.</p> <p>25 Are you asking me to cite to a</p>
Page 47	Page 49
<p>1 Q. All right. And do you see here</p> <p>2 you have replicated language from 21 CFR</p> <p>3 740.1 that reads, "The label of a cosmetic</p> <p>4 product shall bear a warning statement</p> <p>5 whenever necessary or appropriate to prevent</p> <p>6 a health hazard that may be associated with</p> <p>7 the product"?</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. And you added emphasis on</p> <p>11 particular portions of this sentence,</p> <p>12 correct?</p> <p>13 A. Yes, I did that, exactly.</p> <p>14 Q. All right. Now there's a</p> <p>15 clause in this sentence that states,</p> <p>16 "Whenever necessary or appropriate."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. You did not emphasize that</p> <p>20 language; is that correct?</p> <p>21 A. That's correct, I did not.</p> <p>22 Q. What is your understanding</p> <p>23 as -- what you describe as an FDA regulatory</p> <p>24 specialist of the meaning of "whenever</p> <p>25 necessary or appropriate" in 21 CFR 740.1?</p>	<p>1 reference or a part of the regulation</p> <p>2 where they explain it, or what are you</p> <p>3 asking me? Guidance document or --</p> <p>4 QUESTIONS BY MS. BRANSCOME:</p> <p>5 Q. Yes. Can you point me to</p> <p>6 anything other than your personal view of the</p> <p>7 interpretation of this language that would</p> <p>8 tie the requirement "whenever necessary or</p> <p>9 appropriate" to how a product is used?</p> <p>10 MS. PARFITT: Objection. Form.</p> <p>11 THE WITNESS: I'll have to go</p> <p>12 look for you whether there's a</p> <p>13 guidance that states it that way.</p> <p>14 This is based on my experience in</p> <p>15 dealing with the products in the past.</p> <p>16 I think that's also consistent</p> <p>17 with what is described, I would say to</p> <p>18 you, within -- it's consistent -- what</p> <p>19 I'm describing to you, it's consistent</p> <p>20 as well with how the CIR standard for</p> <p>21 safety assessment is done, looking at</p> <p>22 the issue of the -- of the -- of the</p> <p>23 use.</p> <p>24 QUESTIONS BY MS. BRANSCOME:</p> <p>25 Q. When you say that you're basing</p>

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Page 50	Page 52
<p>1 your interpretation of the clause "whenever 2 necessary or appropriate" on your personal 3 experience, can you point me to something 4 specific? 5 MS. PARFITT: Objection. 6 THE WITNESS: Are you asking 7 me -- are you asking me if I've ever 8 had a company that I worked for that 9 that particular clause in here was 10 extremely important to how we 11 interpreted it? I don't think I can 12 point you to that. I don't recall 13 ever having to do that specifically. 14 Or is it something different 15 you're asking me? 16 QUESTIONS BY MS. BRANSCOME: 17 Q. Dr. Plunkett, I asked you what 18 your basis was for interpreting the language 19 "whenever necessary or appropriate" means 20 that it's related to how a product is being 21 used, and the answer that you provided was 22 that it was based off of your personal 23 experience. 24 So I'm asking you, what is that 25 personal experience that gives you the basis</p>	<p>1 look at my documents in order -- the 2 first part of your question, I'd have 3 to go back and look. Off the top of 4 my head, I can't tell what I would 5 point you to. 6 On the second one, I think I 7 was telling you, is I don't -- I've 8 never -- I don't have a client that 9 I've worked for where that part of the 10 language was the only issue that I had 11 to deal with when I'm looking at 12 whether or not the product needs a 13 warning or not. 14 So typically -- I'm just 15 telling you that when I have looked at 16 labeling for products and looked at 17 the issue of does it need a warning 18 statement, when I'm reading it as 19 "whenever necessary or appropriate," 20 I'm looking at whether or not the 21 ingredient that I'm concerned about 22 within the product, how that is used 23 or what the exposure pattern would be, 24 route of exposure, how those things 25 might relate to how I would assess the</p>
Page 51	Page 53
<p>1 for that specific interpretation? 2 MR. MEADOWS: Objection. 3 MS. PARFITT: Objection. 4 THE WITNESS: So it's in my 5 experience in dealing with companies 6 that make products and what types of 7 warnings are put or not put onto -- or 8 not -- or on labeling. So I don't 9 know how else to answer it other than 10 that. 11 I can go back and look at the 12 guidance documents to see if that is 13 described in another way, but I don't 14 recall that. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. So as you sit here today, 17 you're not able to provide me either with a 18 third-party document or an independent 19 document interpreting "whenever necessary or 20 appropriate" as you've suggested today, nor 21 can you give me specific example from your 22 personal experience; is that correct? 23 MS. PARFITT: Objection. 24 THE WITNESS: Well, I 25 certainly -- I'd have to go back and</p>	<p>1 safety issue at hand. And so that's 2 what I'm trying to tell you. 3 QUESTIONS BY MS. BRANSCOME: 4 Q. Okay. You also have -- 5 changing topics a little bit, in this -- in 6 your report marked as Exhibit 4, if you could 7 turn to paragraph 10. 8 On page 7, you state on the 9 first paragraph on page 7, "In other 10 instances I have directed others to perform 11 searches on my behalf," and this is with 12 respect to identifying documents for review 13 in forming your opinions. 14 What did you mean by that? 15 A. So in addition to doing my own 16 searches of the database, sometimes I -- I 17 have called the attorney's office and asked 18 them to -- to do a search for certain things 19 that I'm looking for to add to. So in other 20 words, I have a document I've identified. 21 I'm looking for other documents like that in 22 the large millions and millions of documents 23 that are available. And so sometimes I will 24 ask attorneys to do -- to look in the 25 database for other documents like the ones</p>

14 (Pages 50 to 53)

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Page 54	Page 56
<p>1 that I've identified.</p> <p>2 Q. And without getting into</p> <p>3 anything that would be -- that would call for</p> <p>4 information protected by the attorney/client</p> <p>5 privilege or attorney work product, what</p> <p>6 percentage of the overall searches for</p> <p>7 relevant documents from these particular</p> <p>8 databases that are discussed in paragraph 10</p> <p>9 would you say that you have done yourself as</p> <p>10 opposed to directed others to do?</p> <p>11 A. Well, initially when I first</p> <p>12 started searching, those were my own searches</p> <p>13 exclusively. I would say that more recently,</p> <p>14 in the last year, since I haven't added any</p> <p>15 real new areas but there's new documents that</p> <p>16 have become available, so anything -- any of</p> <p>17 the searches probably in the last year that</p> <p>18 dealt with new discovery that was produced, I</p> <p>19 would have asked the attorneys to do some of</p> <p>20 the searching in that for me. Like I'm</p> <p>21 looking for documents that are similar to</p> <p>22 this document that I cited in my original</p> <p>23 report around this same frame that may be</p> <p>24 discussing this same topic area.</p> <p>25 So in the last year I have</p>	<p>1 A. So that might cross over into</p> <p>2 work product because it's not my database,</p> <p>3 but I don't know how to answer that. I mean,</p> <p>4 I'm sure -- it's very possible that in the</p> <p>5 database you can track that, but I -- I don't</p> <p>6 know.</p> <p>7 MR. MEADOWS: Okay.</p> <p>8 THE WITNESS: I don't have</p> <p>9 anything saved on my computer that</p> <p>10 way, but when you go to the database</p> <p>11 itself, it's possible you could track</p> <p>12 that. I just don't have a record on</p> <p>13 my computer in my office.</p> <p>14 QUESTIONS BY MS. BRANSCOME:</p> <p>15 Q. When you made the decision at</p> <p>16 some point in time -- it may have been even</p> <p>17 prior to you issuing your first report --</p> <p>18 that you wanted to look at company documents,</p> <p>19 did you set out specific categories of</p> <p>20 documents that you wanted to review?</p> <p>21 A. Not so much categories but key</p> <p>22 words. So -- and areas. I guess areas is</p> <p>23 what I -- yes, I was focusing, for example,</p> <p>24 in my initial report on documents that</p> <p>25 described what was known -- what the company</p>
Page 55	Page 57
<p>1 asked them to do that more than I have done</p> <p>2 it, but initially it was what I did</p> <p>3 initially.</p> <p>4 Q. Okay. Do you keep any records</p> <p>5 of the various document searches either that</p> <p>6 you have performed or you have asked to be</p> <p>7 performed?</p> <p>8 A. No, I don't. My record would</p> <p>9 be -- the initial -- the record would have</p> <p>10 been what I listed in my reliance list for</p> <p>11 you in the initial report, but since then it</p> <p>12 would just be what is going to be changing</p> <p>13 within my reliance list, looking at</p> <p>14 additional documents. That's the only way I</p> <p>15 could identify for you. That would be my --</p> <p>16 my trail to know what was new and what was</p> <p>17 not.</p> <p>18 Q. My question is slightly</p> <p>19 different. Understanding that you have</p> <p>20 provided to some extent a record of the</p> <p>21 documents, my question is: Do you have any</p> <p>22 type of record for the nature of the</p> <p>23 searches, what it was that you set out to</p> <p>24 identify in the database and how did you go</p> <p>25 about finding those documents?</p>	<p>1 was discussing about cancer, ovarian cancer,</p> <p>2 cancer generally. So that was a key word</p> <p>3 used.</p> <p>4 And then I also was linking</p> <p>5 that in different searches with different</p> <p>6 time periods such as the NTP review process</p> <p>7 and dates. You can, you know, narrow down by</p> <p>8 dates or by the CIR process. Those kinds of</p> <p>9 things.</p> <p>10 So I did start with that,</p> <p>11 trying to understand what -- what is -- what</p> <p>12 was in the company files or in the files I</p> <p>13 had access to, the database, that dealt with</p> <p>14 those kinds of things because those aren't</p> <p>15 things that I could get to publicly.</p> <p>16 Obviously in the literature. So I had to --</p> <p>17 if I wanted to understand what the company</p> <p>18 knew, I had to go into their database to find</p> <p>19 out, you know, what they knew -- what they</p> <p>20 knew or were discussing over time about the</p> <p>21 ovarian cancer issue or about asbestos in</p> <p>22 talc or about CIR process, things like that.</p> <p>23 Q. Using the reports that you have</p> <p>24 produced, Exhibits 2, 3 and 4, really, and</p> <p>25 the full -- the entirety of the materials</p>

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<p style="text-align: right;">Page 58</p> <p>1 that you have produced in the MDL, is there</p> <p>2 any way that someone reviewing those</p> <p>3 documents, and those documents alone, could</p> <p>4 replicate the searches that you have</p> <p>5 conducted in the company databases?</p> <p>6 MR. MEADOWS: Objection.</p> <p>7 THE WITNESS: I don't know.</p> <p>8 That's a good question. I've never</p> <p>9 thought about whether you could</p> <p>10 replicate or not.</p> <p>11 I mean, I think I've told you</p> <p>12 what I did. My strategy was to focus</p> <p>13 on topic areas. So I think you</p> <p>14 might -- by topic areas, if you use</p> <p>15 the same kinds of topics areas as</p> <p>16 described, I think you would come up</p> <p>17 with documents that -- what it focused</p> <p>18 down to.</p> <p>19 For example, I also would</p> <p>20 sometimes, as linking those words, I</p> <p>21 might put in J&J documents only or</p> <p>22 Imerys documents only, because the</p> <p>23 database has a variety -- and the</p> <p>24 PCPC. There's some different ways by</p> <p>25 the Bates numbers that you can</p>	<p style="text-align: right;">Page 60</p> <p>1 reliance list, that you read, but then once</p> <p>2 you started reading decided weren't relevant</p> <p>3 to the opinions that you were offering?</p> <p>4 A. I would have to look to answer</p> <p>5 that for you. I don't know. If you want me</p> <p>6 to do that, I'd have to look.</p> <p>7 Q. I ask you more as a process</p> <p>8 matter.</p> <p>9 A. Oh.</p> <p>10 Q. If you pull an article and you</p> <p>11 start reading it and you realize that it is</p> <p>12 not relevant to the opinions that you offered</p> <p>13 in this case, the example that you just gave,</p> <p>14 is it something that you would include in</p> <p>15 your reliance list?</p> <p>16 A. Yes, I -- I have given you</p> <p>17 everything I retrieved. So if I retrieved</p> <p>18 it, you would have, yes, absolutely.</p> <p>19 Q. Okay. So it's fair to say of</p> <p>20 the articles that are on your reliance list,</p> <p>21 you could not say as you sit here today that</p> <p>22 you have read each and every word of each and</p> <p>23 every one of them, correct?</p> <p>24 A. That's correct. And I could</p> <p>25 probably tell you -- I could give you a</p>
<p style="text-align: right;">Page 59</p> <p>1 segregate documents as well. But I</p> <p>2 don't know other than that. That's</p> <p>3 all I can tell you.</p> <p>4 QUESTIONS BY MS. BRANSCOME:</p> <p>5 Q. You would agree with me that</p> <p>6 your report does not contain a complete</p> <p>7 explanation of the process by which you</p> <p>8 identify company documents to review,</p> <p>9 correct?</p> <p>10 A. I haven't laid out my search</p> <p>11 structure, that is true.</p> <p>12 Q. All right. Now, the articles</p> <p>13 that you have listed on your reliance list,</p> <p>14 have you read each and every one of those</p> <p>15 articles?</p> <p>16 A. Unfortunately, yes, over time I</p> <p>17 have. Some of them I have only read parts of</p> <p>18 them. For example, if I started reading a</p> <p>19 document and I felt that it was something I</p> <p>20 pulled that really wasn't directly on point</p> <p>21 for an area I'm covering, I may not have read</p> <p>22 every word, but certainly I have been through</p> <p>23 each of those, yes.</p> <p>24 Q. Are there any articles in your</p> <p>25 reliance list, that you maintained on your</p>	<p style="text-align: right;">Page 61</p> <p>1 little guidance in that possibly if I went to</p> <p>2 my list, I could try to pull some out that I</p> <p>3 recognize, but that's all I would be able to</p> <p>4 do for you.</p> <p>5 Q. Okay. How did you go about</p> <p>6 identifying what articles you wanted to</p> <p>7 review in forming your opinions in the MDL?</p> <p>8 A. So first off, I went back to</p> <p>9 what I already had. So my MDL report is a --</p> <p>10 is a compilation of a lot of material that's</p> <p>11 in my first few reports. That was the basis</p> <p>12 for some of the things that went into it.</p> <p>13 So I didn't -- I did do,</p> <p>14 though, a updating on literature searches for</p> <p>15 the MDL report, looking for anything new, for</p> <p>16 example, in the area, especially the area of</p> <p>17 cancer data or reports of dealing with</p> <p>18 ovarian cancer either -- or any articles</p> <p>19 dealing with the link between inflammation</p> <p>20 and cancer, ovarian cancer, generally.</p> <p>21 That's one of the areas I updated looking at.</p> <p>22 And then I did -- I don't think</p> <p>23 I did any large, new searches, however,</p> <p>24 because honestly the areas covered here are a</p> <p>25 little narrower than what was covered here.</p>

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Page 62	Page 64
<p>1 I don't believe that there was any from the</p> <p>2 published -- the publicly available medical</p> <p>3 literature. There wasn't a need to do a</p> <p>4 whole new area of search. It was more</p> <p>5 updating the things that I've done in the</p> <p>6 past.</p> <p>7 So it's a real easy search to</p> <p>8 update because you can just put in talc and</p> <p>9 cancer and just look at -- get lots, but you</p> <p>10 can then just start chronologically and look</p> <p>11 what was published in the last year, for</p> <p>12 example.</p> <p>13 Q. Okay. Earlier when we were</p> <p>14 discussing the fact that you in some</p> <p>15 instances have asked your husband to pull</p> <p>16 articles, have you maintained any records of</p> <p>17 the searches that you have done with respect</p> <p>18 to scientific literature, including the</p> <p>19 searches that you have asked your husband to</p> <p>20 do?</p> <p>21 A. I have not. It's possible that</p> <p>22 there are records on billing from the library</p> <p>23 that tells you how many I ordered at</p> <p>24 different times, but that is the only</p> <p>25 records, because we do have to pay the</p>	<p>1 referring to the reliance list, are you</p> <p>2 referring to the list of articles that begins</p> <p>3 on page 40 of Exhibit 4, or is there a</p> <p>4 separate document?</p> <p>5 A. There's a separate document.</p> <p>6 So it -- that's -- I usually call reliance</p> <p>7 list the separate document. I call this</p> <p>8 references cited. So I apologize for that</p> <p>9 confusion.</p> <p>10 So these, I have read every</p> <p>11 word. If it's in my reference list, those</p> <p>12 are not an issue of not having read every</p> <p>13 word, and these should all be cited somewhere</p> <p>14 in the report.</p> <p>15 Q. Okay. If you could turn to</p> <p>16 paragraph 21 in your initial report.</p> <p>17 A. Yes, I'm there.</p> <p>18 Q. Okay. So we're looking at</p> <p>19 paragraph 21 in Exhibit 2. This is on</p> <p>20 page 10.</p> <p>21 Do you see there is a sentence</p> <p>22 here that refers to -- it's referring</p> <p>23 generally to the topic of the ability of talc</p> <p>24 to migrate from the site of application to</p> <p>25 the ovaries.</p>
Page 63	Page 65
<p>1 library for the retrieval.</p> <p>2 Q. Okay. And if I understood what</p> <p>3 you said earlier correctly, you indicated</p> <p>4 that any article you have ever pulled for</p> <p>5 review, you have listed on your reliance</p> <p>6 list; is that correct?</p> <p>7 A. Yes. And when I -- and let's</p> <p>8 just make sure we're talking about the same</p> <p>9 thing.</p> <p>10 So, you know, in my reports I</p> <p>11 typically have articles cited in the report</p> <p>12 separate from the reliance list. So I'm</p> <p>13 talking about the reliance list, right?</p> <p>14 Okay.</p> <p>15 So -- because I do -- I do</p> <p>16 usually -- I don't know whether I did that in</p> <p>17 this report, but I typically have a list of</p> <p>18 articles cited at the back called references,</p> <p>19 that is, things that you're actually seeing</p> <p>20 in the report body, and then there should be</p> <p>21 a separate reliance list sent to you as an</p> <p>22 appendix. I don't know what the appendix</p> <p>23 was.</p> <p>24 Q. Well, so then let's clarify</p> <p>25 that. So, Dr. Plunkett, when you're</p>	<p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And then the next sentence</p> <p>4 states, "This issue was discussed by</p> <p>5 scientific and regulatory bodies that review</p> <p>6 the toxicokinetics of talc."</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And in parentheses it</p> <p>10 identified EPA 1992, IARC 2010, and CIR 2013.</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And then if you could</p> <p>14 turn to Exhibit 4, which is your MDL report,</p> <p>15 at paragraph 43. It's on page 28.</p> <p>16 Are you with me?</p> <p>17 A. Yes, I am.</p> <p>18 Q. You see that the exact same</p> <p>19 sentence appears -- well, not the exact same.</p> <p>20 It's been slightly modified to combine the</p> <p>21 first two sentences. But here you cite only</p> <p>22 to EPA 1992 and IARC 2010.</p> <p>23 Why did you remove CIR 2013?</p> <p>24 A. Because of my further</p> <p>25 evaluation since my initial report in 2016 of</p>

17 (Pages 62 to 65)

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Page 66	Page 68
<p>1 the process that was involved in the drafting</p> <p>2 of the CIR and the actual production of the</p> <p>3 report.</p> <p>4 Q. Is it your position that the</p> <p>5 migration of talc was not evaluated as part</p> <p>6 of CIR 2013?</p> <p>7 A. No. That's not my position,</p> <p>8 no.</p> <p>9 Q. Okay. And so would the</p> <p>10 sentence that's contained in paragraph 43 in</p> <p>11 Exhibit 4, which is your MDL report, if you</p> <p>12 cited to CIR 2013 in the parenthetical there,</p> <p>13 would that not be an accurate citation?</p> <p>14 A. I believe it would not be an</p> <p>15 accurate citation because I have formed</p> <p>16 opinions about the reliability of that</p> <p>17 document at this point in time.</p> <p>18 So it has to do with -- I'm</p> <p>19 citing to authorities here that I believe are</p> <p>20 reliable as far as the discussion that I see,</p> <p>21 and it's a different -- I have a different</p> <p>22 opinion now about the CIR report, which I lay</p> <p>23 out in pretty detail, I think.</p> <p>24 In fact, if you go to my</p> <p>25 section following this now in -- you'll</p>	<p>1 another question. In paragraph 43, you added</p> <p>2 two studies from your prior -- that were --</p> <p>3 that did not appear in your prior report, and</p> <p>4 it was Gardner 1981 and Edelstam 1997. This</p> <p>5 related to animal studies showing that in</p> <p>6 some species talc can migrate from the lower</p> <p>7 to the upper genital tract?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Were those studies that</p> <p>10 you were aware of before drafting your prior</p> <p>11 reports?</p> <p>12 A. I don't know that they -- I</p> <p>13 can't answer that without looking at my</p> <p>14 reliance materials for the original report.</p> <p>15 I did identify additional articles, and</p> <p>16 there's also additional articles cited here</p> <p>17 in earlier paragraph 43 that were not cited</p> <p>18 in my original report as well. I don't think</p> <p>19 I had the -- the Kunz article then cited.</p> <p>20 I'd have to go back and look.</p> <p>21 So it's possible that they were</p> <p>22 in my -- when I say my reliance materials, my</p> <p>23 original report also had a larger list of</p> <p>24 literature I didn't cite. So I'd have to</p> <p>25 look. I can't tell you whether I had them or</p>
Page 67	Page 69
<p>1 understand one of the issues I had was the --</p> <p>2 the difference in the evidence that was</p> <p>3 actually available once you dig into it a</p> <p>4 little further versus what they actually</p> <p>5 reviewed. That's one of the issues.</p> <p>6 Q. And I'll follow up with some</p> <p>7 more questions about the CIR, but my question</p> <p>8 here is, the sentence in your report simply</p> <p>9 states, "The migration of talc internally</p> <p>10 after perineal application was discussed by</p> <p>11 scientific and regulatory bodies that review</p> <p>12 the toxicokinetics of talc."</p> <p>13 Would it be inaccurate to say</p> <p>14 that as part of the CIR 2013 process that</p> <p>15 body did, in fact, discuss the migration of</p> <p>16 talc internally after perineal application?</p> <p>17 A. It is true that they did</p> <p>18 discuss it. I just have an issue with the</p> <p>19 reliability of their findings.</p> <p>20 Q. And so you made the decision to</p> <p>21 just remove it from the citation; is that</p> <p>22 correct?</p> <p>23 A. Yes, at this point -- at this</p> <p>24 point, at this report, that's exactly right.</p> <p>25 Q. All right. And then I had</p>	<p>1 I did not.</p> <p>2 Q. Okay. With respect to Edelstam</p> <p>3 1997 study, do you happen to know the title</p> <p>4 of that article? Even an approximation would</p> <p>5 work.</p> <p>6 A. It'll be -- should be back</p> <p>7 here. Just a second. If it's not here,</p> <p>8 that's a mistake.</p> <p>9 Oh, here it is. "Retrograde</p> <p>10 migration of starch in the genital tract of</p> <p>11 rabbits."</p> <p>12 Q. So you are citing that article</p> <p>13 for the proposition that animal studies have</p> <p>14 demonstrated that talc can migrate from the</p> <p>15 lower to upper genital tract?</p> <p>16 A. Yes, I'm citing it because it's</p> <p>17 relevant to the issue of particle migration,</p> <p>18 which talc is a particle. So, yes, that's</p> <p>19 correct.</p> <p>20 Q. Okay. But that study did not</p> <p>21 specifically deal with talc migration,</p> <p>22 correct?</p> <p>23 A. No. Well, it -- it's relevant</p> <p>24 to talc migration, but you're exactly right,</p> <p>25 they looked at the starch migration, yes. Or</p>

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Page 70	Page 72
<p>1 particles that were starch, yes.</p> <p>2 Q. We'll cover this in more</p> <p>3 detail, but is it your opinion that all</p> <p>4 particles have similar characteristics with</p> <p>5 respect to their ability to migrate in the</p> <p>6 genital tract?</p> <p>7 A. It's my -- I don't know if I'd</p> <p>8 state it quite that way. What I would say is</p> <p>9 that the evidence shows that particles</p> <p>10 generally have the ability to move up the</p> <p>11 reproductive tract in women, yes, and that if</p> <p>12 a particle is one that is similar to talc or</p> <p>13 some of the other ones where the information</p> <p>14 has been collected, I would characterize that</p> <p>15 as being within that, quote/unquote,</p> <p>16 relevance of particles.</p> <p>17 That doesn't mean all</p> <p>18 particles, but certainly in the ones that I</p> <p>19 have looked at and the data I've relied upon,</p> <p>20 there's a variety of different types of</p> <p>21 particles or substances that have been</p> <p>22 studied and shown to be able to migrate.</p> <p>23 Q. So let's take Edelstam 1997 as</p> <p>24 an example.</p> <p>25 Did you do any analysis that</p>	<p>1 genital tract?</p> <p>2 MS. PARFITT: Objection.</p> <p>3 THE WITNESS: Again, I haven't</p> <p>4 done an in-depth analysis. I mean, as</p> <p>5 a toxicologist, there are differences</p> <p>6 between starch and talc, absolutely.</p> <p>7 For example, starch would -- I would</p> <p>8 expect to be more easily solubilized</p> <p>9 within fluids, and so that could</p> <p>10 affect the ability of them to actually</p> <p>11 not migrate as well as a talc</p> <p>12 particle, which would be less soluble</p> <p>13 than the starch would be.</p> <p>14 And there's -- I even --</p> <p>15 there's a paper I have in here, and I</p> <p>16 can look for it if you want, that</p> <p>17 talks about that difference, and it's</p> <p>18 one of the issues of cornstarch versus</p> <p>19 talc, on whether or not you would</p> <p>20 expect to get the long-term chronic</p> <p>21 responses with the difference between</p> <p>22 those two substances.</p> <p>23 So I do think there's</p> <p>24 difference, absolutely, as</p> <p>25 toxicologists generally. And the only</p>
Page 71	Page 73
<p>1 you can point me to that establishes that</p> <p>2 starch would have a similar migration pattern</p> <p>3 as talc?</p> <p>4 A. So I would say that the paper</p> <p>5 itself shows -- talks about the movement of</p> <p>6 starch, but are you asking something</p> <p>7 different?</p> <p>8 Are you asking me have I done a</p> <p>9 specific analysis of any differences that may</p> <p>10 occur between the migration pattern of starch</p> <p>11 and talc? Is that what you're asking me?</p> <p>12 Q. That is what I'm asking you.</p> <p>13 A. I certainly didn't do an</p> <p>14 in-depth analysis of the differences, no, but</p> <p>15 based upon my review of the literature, I</p> <p>16 believe that that paper is relevant to the</p> <p>17 overall question of migration of particulate</p> <p>18 through the reproductive tract, including</p> <p>19 particles of talc.</p> <p>20 Q. Regardless of whether or not it</p> <p>21 was an in-depth analysis, can you point me to</p> <p>22 anything other than just your belief after</p> <p>23 having read these articles that starch and</p> <p>24 talc would have similar migratory</p> <p>25 characteristics in the human or animal</p>	<p>1 reason I'm citing this paper is</p> <p>2 because I'm trying to be complete</p> <p>3 about people that have looked at this</p> <p>4 issue. And certainly it was a study</p> <p>5 that looked at this issue and talks</p> <p>6 about the movement.</p> <p>7 But I wouldn't expect starch</p> <p>8 and the talc to have the same</p> <p>9 liabilities, and I also wouldn't</p> <p>10 expect them to move exactly the same</p> <p>11 speed maybe. That's very true.</p> <p>12 QUESTIONS BY MS. BRANSCOME:</p> <p>13 Q. So you would agree with me that</p> <p>14 Edelstam is not a study demonstrating that</p> <p>15 talc can migrate from the lower to upper</p> <p>16 genital tract, correct?</p> <p>17 MS. PARFITT: Objection. Form.</p> <p>18 THE WITNESS: I wouldn't say it</p> <p>19 that way. What I would say instead is</p> <p>20 that Edelstam is a study that forms</p> <p>21 the overall weight of the evidence for</p> <p>22 the ethics -- for the studies that are</p> <p>23 available that address the issue of</p> <p>24 migration, but certainly it is not</p> <p>25 studying talc. So I don't disagree</p>

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<p style="text-align: right;">Page 74</p> <p>1 with you there.</p> <p>2 Unfortunately, the majority of</p> <p>3 the information that I have relied</p> <p>4 upon, and others such as the FDA in</p> <p>5 making their statements about</p> <p>6 migration, is not all directed studies</p> <p>7 just to talc. It's looking at the</p> <p>8 issue of particle movement.</p> <p>9 QUESTIONS BY MS. BRANSCOME:</p> <p>10 Q. Now, in terms of doing your</p> <p>11 risk assessment -- well, let me get back. We</p> <p>12 covered this earlier, and I want to return to</p> <p>13 it for a moment. Just to confirm: For your</p> <p>14 work in the MDL, you did not do a Bradford</p> <p>15 Hill analysis, correct?</p> <p>16 A. I did not sit down and do a</p> <p>17 Bradford Hill analysis when I started writing</p> <p>18 this report. I have done a Bradford Hill</p> <p>19 analysis in the past, which is in my original</p> <p>20 reports, but I certainly did not redo a</p> <p>21 Bradford Hill when I sat down to draft my MDL</p> <p>22 report, that is true.</p> <p>23 Q. Okay. Let me be more precise.</p> <p>24 In the report that you have</p> <p>25 produced that contains a description of your</p>	<p style="text-align: right;">Page 76</p> <p>1 assessment.</p> <p>2 Q. Okay. What publication would</p> <p>3 you direct me to that has used the same</p> <p>4 methodology that you have used to reach your</p> <p>5 opinions in Exhibit 4?</p> <p>6 A. I think I cite you to -- cite</p> <p>7 you to some of those. You could -- well, the</p> <p>8 directly relevant one would be looking at the</p> <p>9 chapter on risk -- toxicology in the</p> <p>10 reference manual on scientific evidence.</p> <p>11 You can also go to the NRC</p> <p>12 report where they -- it lays out the</p> <p>13 different steps that you use when you kind of</p> <p>14 break data apart into exposure versus</p> <p>15 response information.</p> <p>16 And then I cite to -- there are</p> <p>17 some guidance documents that I cite to, and</p> <p>18 this is in paragraph 13. And I'd have to</p> <p>19 pull them out again to tell you which ones</p> <p>20 relate to different pieces because some of</p> <p>21 these are -- some of these documents are</p> <p>22 specific to only, for example, maybe one part</p> <p>23 of what I did.</p> <p>24 But certainly the risk</p> <p>25 assessment process at IARC is -- they do what</p>
<p style="text-align: right;">Page 75</p> <p>1 opinions in the MDL, you have not set forth a</p> <p>2 Bradford Hill analysis in that document which</p> <p>3 is identified as Exhibit 4, correct?</p> <p>4 A. That is true, yes.</p> <p>5 MS. PARFITT: Objection.</p> <p>6 QUESTIONS BY MS. BRANSCOME:</p> <p>7 Q. And in fact, the paragraph that</p> <p>8 you -- or paragraphs that you have in your</p> <p>9 prior reports that reference a Bradford Hill</p> <p>10 analysis, those have not -- those have</p> <p>11 actually not been replicated in any form in</p> <p>12 Exhibit 4, correct?</p> <p>13 A. Yes, because, again, it was not</p> <p>14 my role to do general cause.</p> <p>15 Q. Okay. So then when we look at</p> <p>16 the methodology that you employed in reaching</p> <p>17 your opinions that are contained here in</p> <p>18 Exhibit 4, how would you characterize the</p> <p>19 methodology?</p> <p>20 A. As I have in the report. I</p> <p>21 talk about it being a risk assessment or a</p> <p>22 safety assessment, that you could use those</p> <p>23 terms interchangeably here. And then I've</p> <p>24 also used a weight of the evidence as a tool</p> <p>25 to go through the different steps of the risk</p>	<p style="text-align: right;">Page 77</p> <p>1 I call a hazard assessment. They identify</p> <p>2 hazard and they couldn't quantify risk, but</p> <p>3 the steps they go through are essentially the</p> <p>4 same types of steps that I went through as</p> <p>5 far as gathering data on not just response</p> <p>6 but also the potential for exposure and how</p> <p>7 that relates to the response.</p> <p>8 And then also the data that</p> <p>9 I've collected on the biologic effects of</p> <p>10 talc, toxicology of talc, are also discussed</p> <p>11 within that document as well.</p> <p>12 Q. Okay. Focusing specifically on</p> <p>13 the weight of the evidence tool, as you</p> <p>14 describe it, is there a particular document</p> <p>15 or publication that I would go to that could</p> <p>16 lay out the same process that you used for</p> <p>17 how you weighted certain pieces of evidence?</p> <p>18 A. So the documents that I've</p> <p>19 cited for you in paragraph 13 talk about what</p> <p>20 weight of the evidence is generally, but if</p> <p>21 you read what it is, it's essentially a</p> <p>22 process that each scientist brings their</p> <p>23 experience, training and judgment to.</p> <p>24 So I try to lay out for you in</p> <p>25 my discussion of the literature my thought</p>

20 (Pages 74 to 77)

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Page 78	Page 80
<p>1 process as I review each piece of</p> <p>2 information, and that is what you do as part</p> <p>3 of weight of the evidence. You gather all of</p> <p>4 the relevant information that you can find</p> <p>5 that address the question you're trying to</p> <p>6 answer, and since I'm looking at both</p> <p>7 exposure and response, I gather different</p> <p>8 pools of information.</p> <p>9 Q. You would agree that there are</p> <p>10 ways to do a weight of the evidence</p> <p>11 assessment of published literature that</p> <p>12 assign, for example, quantitative values to</p> <p>13 particular pieces of evidence, correct?</p> <p>14 A. Certain individuals have put</p> <p>15 together, but there's no one general accepted</p> <p>16 process that everyone uses. So I -- that's</p> <p>17 the issue. Again, there are certain --</p> <p>18 certain cases where I've seen that done, and</p> <p>19 then there are many -- most cases that it's</p> <p>20 not what's done.</p> <p>21 Q. Okay.</p> <p>22 A. Another body, by the way, that</p> <p>23 I -- it's new. It's not in paragraph 13. I</p> <p>24 just want to make sure I tell you that so</p> <p>25 we're clear. If you look at the Canadian</p>	<p>1 Q. Okay. As you were forming your</p> <p>2 opinions, Dr. Plunkett, about whether or not</p> <p>3 there is a risk associated with the use of</p> <p>4 Johnson's baby powder with respect to ovarian</p> <p>5 cancer, how do you keep track of the pieces</p> <p>6 of scientific evidence that you have reviewed</p> <p>7 and the respective weight that you give to</p> <p>8 them?</p> <p>9 Presumably you did not read</p> <p>10 everything in one day, for example?</p> <p>11 A. No. That's correct. So I</p> <p>12 typically will -- I typically will save the</p> <p>13 papers -- when I read the papers, I will</p> <p>14 often highlight in yellow information that I</p> <p>15 think is going to -- will be extremely</p> <p>16 relevant. I don't put notes on the document.</p> <p>17 I highlight in yellow on the PDF file to use</p> <p>18 that to write.</p> <p>19 And I also start drafting</p> <p>20 report very early, which then gets</p> <p>21 overwritten and actually ends up looking like</p> <p>22 an outline that eventually becomes the</p> <p>23 report.</p> <p>24 So one of the ways I keep track</p> <p>25 of things is I may put a paragraph name that</p>
Page 79	Page 81
<p>1 document, they also -- in fact, a lot of what</p> <p>2 they have, you'll see the same literature</p> <p>3 described within my assessment as well.</p> <p>4 Q. So using the Canadian</p> <p>5 assessment as an example, for instance, in</p> <p>6 that assessment there were actually values</p> <p>7 assigned to particular pieces of literature,</p> <p>8 correct?</p> <p>9 A. Mainly the epidemiological</p> <p>10 literature, that is true. Again, but I'm not</p> <p>11 doing causation, so I didn't approach it that</p> <p>12 way.</p> <p>13 But certainly if you look at</p> <p>14 what I did, it's consistent with that because</p> <p>15 I talk about the differences between the</p> <p>16 limitations of a case-control versus a</p> <p>17 prospective study. I talk about both the</p> <p>18 positives and the negatives within the</p> <p>19 database, but I don't lay it out in a table</p> <p>20 like they do. But it's certainly the same</p> <p>21 basic process.</p> <p>22 I was actually quite surprised</p> <p>23 at how similar the database of information</p> <p>24 that they reviewed was to what I honed in on</p> <p>25 as well.</p>	<p>1 I know I'm going to write, such as exposure</p> <p>2 migration, and then I -- as I'm reading a</p> <p>3 paper, I'll type in a paper -- the ones that</p> <p>4 I believe are important to my overall</p> <p>5 assessment. So I will do that as I'm -- as</p> <p>6 I'm going through the evidence.</p> <p>7 So that's one of the tools I</p> <p>8 use, but I don't keep notes. I just kind of</p> <p>9 use that as a living document that eventually</p> <p>10 becomes a report.</p> <p>11 Q. Do your opinions ever change as</p> <p>12 you read additional pieces of scientific</p> <p>13 evidence?</p> <p>14 A. Yes, it does. It may change.</p> <p>15 And it often -- often the changes, though,</p> <p>16 are not that I believe -- with the exception</p> <p>17 of epidemiology. In other areas.</p> <p>18 Epidemiology is a little bit different issue</p> <p>19 when you're reviewing studies.</p> <p>20 But on toxicology I always</p> <p>21 start with reviews and regulatory</p> <p>22 authorities, looking at what others have said</p> <p>23 generally about the toxicology. And so even</p> <p>24 though I may refine opinions differently or I</p> <p>25 might change, I certainly wouldn't agree to</p>

21 (Pages 78 to 81)

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Page 82	Page 84
<p>1 work on a project to start with if my initial</p> <p>2 reviews on hazard, for example, didn't</p> <p>3 convince me that I believe that there is a</p> <p>4 hazard. But you refine it from there.</p> <p>5 That's exactly right.</p> <p>6 So there are cases, however,</p> <p>7 where I'm asked to work on a project where</p> <p>8 there is no review or regulatory authority or</p> <p>9 any kind of assessment over a period of</p> <p>10 years, and in those cases there are times</p> <p>11 when I start working on a project and I stop</p> <p>12 and say, "I can't do this." Because that</p> <p>13 happens, yes.</p> <p>14 So opinions do change sometimes</p> <p>15 based on review of additional information.</p> <p>16 Q. Is there any documentation that</p> <p>17 you've produced either in your report or</p> <p>18 otherwise in the MDL that would allow someone</p> <p>19 reviewing the material to understand the</p> <p>20 order in which you reviewed materials or the</p> <p>21 specific weight that you assign them?</p> <p>22 A. So order of review, no. I</p> <p>23 don't think you would know that other than --</p> <p>24 you will note order of review if you look at</p> <p>25 the differences in the literature cited in my</p>	<p>1 your report that have been criticized by</p> <p>2 others at some point in time, correct?</p> <p>3 A. Yes, that's true.</p> <p>4 Q. Okay. Now, in some instances</p> <p>5 you state that you then give little weight to</p> <p>6 those studies, correct?</p> <p>7 A. Yes.</p> <p>8 Q. But in other instances you find</p> <p>9 the criticized study to be helpful and</p> <p>10 informative, correct?</p> <p>11 A. That's true. Because, again,</p> <p>12 judgment -- as anybody does weight of the</p> <p>13 evidence, different scientists can have</p> <p>14 different judgment.</p> <p>15 Mainly, I think, when I look at</p> <p>16 the differences in that -- in that regard, I</p> <p>17 think you should pay attention to what the</p> <p>18 person is. So as a toxicologist, I may view</p> <p>19 a certain type of -- piece of data very</p> <p>20 differently than an epidemiologist may view</p> <p>21 it, as far as the reliability or the</p> <p>22 relevance, because we're coming at it from a</p> <p>23 different training and experience and</p> <p>24 judgment -- set of judgment on what is</p> <p>25 important to a toxicologist when I'm talking</p>
Page 83	Page 85
<p>1 original report versus in the MDL.</p> <p>2 So in my original reliance</p> <p>3 list, if there were documents that weren't</p> <p>4 there and they're now here, obviously that</p> <p>5 tells you it was a review.</p> <p>6 On the issue of a -- of the</p> <p>7 weight of the evidence process, the only</p> <p>8 answer I can give you for that is that</p> <p>9 articles that I believe are -- are reliable,</p> <p>10 are relevant and are -- those are kind of</p> <p>11 the -- you look at the reliability of the</p> <p>12 studies, whether they're peer-reviewed or not</p> <p>13 or if they have proper controls put into</p> <p>14 place, things like that, whether or not</p> <p>15 the -- they're relevant to the question at</p> <p>16 hand. That you can get from looking at how I</p> <p>17 discuss them in the document. But certainly</p> <p>18 there's no, like, summary of that.</p> <p>19 But certainly -- I think you</p> <p>20 understand -- you should understand when you</p> <p>21 read my report what weight I'm giving based</p> <p>22 on how I'm describing those -- those</p> <p>23 materials. I mean, it's --</p> <p>24 Q. Well, for example, you do have</p> <p>25 different studies that you've identified in</p>	<p>1 about risk versus how an epidemiologist might</p> <p>2 talk about risk.</p> <p>3 Q. Could two different</p> <p>4 toxicologists review the same piece of</p> <p>5 literature and give it very different weight?</p> <p>6 A. I don't know about different</p> <p>7 weight, but they certainly -- I know people</p> <p>8 come to different conclusions based on their</p> <p>9 overall assessments. That happens,</p> <p>10 definitely. I mean, there are always going</p> <p>11 to be individuals that look at things</p> <p>12 differently.</p> <p>13 I know in this case there are</p> <p>14 people -- I've seen defense experts that</p> <p>15 reports in -- not in the MDL but in other</p> <p>16 cases, where people disagree with some of my</p> <p>17 opinions, and I disagree with their opinions.</p> <p>18 That happens.</p> <p>19 Q. Okay. And so if I were --</p> <p>20 well, let me just ask something. You have</p> <p>21 not provided any sort of quantitative</p> <p>22 assessment of the weight that you gave</p> <p>23 different pieces of evidence that you cite in</p> <p>24 forming your opinions in the MDL, correct?</p> <p>25 MS. PARFITT: Objection.</p>

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<p style="text-align: right;">Page 86</p> <p>1 Misstates her testimony. 2 MR. MEADOWS: Objection. 3 THE WITNESS: So I don't report 4 for you a table where I quantify that, 5 that is correct, but certainly that 6 is -- because, again, based upon 7 looking at the way that I was trained 8 and the documents that I'm talking -- 9 I'm pointing you to to describe how to 10 do weight of the evidence, it is 11 not -- it is not a numerical exercise, 12 how many here, how many there, this 13 one gets 5 points because of this or 14 6 points because of this. 15 It's more an issue, again, of 16 judgment. It's the idea of looking 17 across all of the available 18 information and determining whether or 19 not, based on that, it's your opinion 20 that there -- that, for example, 21 talc -- talc's toxicity profile 22 includes cancer. That's one of the 23 judgments -- weight of the evidence 24 judgments you make, for example. 25</p>	<p style="text-align: right;">Page 88</p> <p>1 you're looking at. 2 The robustness of the data. 3 For example, the NTP GLP quality 4 animal study, very high quality in the 5 weight of the evidence. And I talked 6 to you about that. In fact, it -- 7 even though people criticize that 8 study, that study is very valuable for 9 looking at biologic changes that are 10 consistent with a carcinogenic 11 mechanism being initiated. 12 So even though you may say that 13 you can't quantify risk from that 14 animal study as far as calculating a 15 cancer potency factor, what you can do 16 is use that study of high quality to 17 make judgments within a weight of the 18 evidence for risk. 19 QUESTIONS BY MS. BRANSCOME: 20 Q. Dr. Plunkett, you understand I 21 have seven hours today, and I -- while I'm 22 very interested in the answers that you give, 23 if we could just -- we will get to things 24 like NTP when we get there, if you could just 25 attempt to answer the question that I've</p>
<p style="text-align: right;">Page 87</p> <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. So -- but, Dr. Plunkett, just 3 to be clear, you do not provide a numerical 4 value to the particular pieces of evidence 5 that you have considered as part of your 6 weight of the evidence assessment in the MDL, 7 correct? 8 MS. PARFITT: Objection. Form. 9 THE WITNESS: So I do not 10 provide a numerical value as you see 11 it laid out, for example, in the 12 Canadian table, but certainly I do 13 judge articles that I include in my 14 weight of the evidence based on a 15 system that includes different 16 considerations such as -- like I said, 17 peer-reviewed or not, that makes an 18 issue. 19 Whether or not the study that's 20 being reported is the only one -- the 21 first or is this something that is -- 22 that is describing an assessment 23 that's been done by someone else and 24 so you see a repetition or a 25 consistency among the studies that</p>	<p style="text-align: right;">Page 89</p> <p>1 asked. 2 I simply asked the question: 3 Are there numerical values assigned to the 4 particular pieces of evidence that you have 5 considered as part of your weight of the 6 evidence assessment in reaching your opinions 7 in the MDL; yes or no? 8 A. And I said to you, not in the 9 way that it's done -- I assume you're 10 referring to something like what was done -- 11 what's in the Canadian epidemiology table. I 12 have not done that, no. 13 Q. Okay. 14 A. That's exactly right. 15 Q. Have you provided a qualitative 16 chart, for example, of the evidence that you 17 have considered in forming your opinions in 18 the MDL? 19 MS. PARFITT: Objection. Form. 20 THE WITNESS: I don't know what 21 you mean by qualitative chart. I 22 certainly have -- I certainly, I 23 believe, have given you qualitative 24 descriptions of my weight within my 25 discussions of each study, yes, I have</p>

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Page 90	Page 92
<p>1 done that.</p> <p>2 QUESTIONS BY MS. BRANSCOME:</p> <p>3 Q. You mention in response to the</p> <p>4 prior question that you have a system for</p> <p>5 weighting the pieces of evidence that you</p> <p>6 have reviewed.</p> <p>7 Can you point me to paragraphs</p> <p>8 in your report marked Exhibit 4 that would</p> <p>9 outline in detail the system that you used to</p> <p>10 apply different weight analysis to different</p> <p>11 pieces of evidence?</p> <p>12 MS. PARFITT: Objection. Form.</p> <p>13 THE WITNESS: And I think I</p> <p>14 answered that, that there's no system</p> <p>15 written down by anyone. But what</p> <p>16 there is, instead, is if you read</p> <p>17 these -- if you read these</p> <p>18 descriptions of use of weight of the</p> <p>19 evidence that I've cited in</p> <p>20 paragraph 13 as well as the discussion</p> <p>21 of methodology in the Canadian</p> <p>22 document, that is consistent with what</p> <p>23 I do. It's the idea that you start</p> <p>24 with a literature search for</p> <p>25 peer-reviewed, publicly available</p>	<p>1 published afterwards, and what I</p> <p>2 thought I said to you was that if you</p> <p>3 look at that document -- it's not in</p> <p>4 paragraph 13, but if you look at that</p> <p>5 document, it lays out a process. And</p> <p>6 I wouldn't call it a system. It's a</p> <p>7 process. It's a process by which you</p> <p>8 screen information for relevance to</p> <p>9 the question being asked and how,</p> <p>10 then, based on that, you look at</p> <p>11 characteristics of that information</p> <p>12 such as -- and I tried to give you</p> <p>13 some of those.</p> <p>14 And I've said this before in</p> <p>15 depositions in these cases. You know,</p> <p>16 you look at the issue of whether or</p> <p>17 not the study was peer-reviewed,</p> <p>18 whether or not there was</p> <p>19 statistically -- statistical</p> <p>20 significance or at least statistics</p> <p>21 applied to the data. What was the</p> <p>22 quality of the study as far as the</p> <p>23 size in order to be able to answer the</p> <p>24 question being asked. Those are the</p> <p>25 kinds of things that you look at.</p>
Page 91	Page 93
<p>1 information. You look at the quality</p> <p>2 of the studies, the statistically</p> <p>3 significant findings. Those are all</p> <p>4 things that are discussed within these</p> <p>5 documents I'm pointing you to.</p> <p>6 QUESTIONS BY MS. BRANSCOME:</p> <p>7 Q. Now, you --</p> <p>8 A. But it's -- it's -- I don't</p> <p>9 know of anyone who has written down a</p> <p>10 specific system that applies in all</p> <p>11 circumstances, no.</p> <p>12 Q. Okay. Have you written down a</p> <p>13 system that applies specifically in this</p> <p>14 case?</p> <p>15 A. I think I have tried to do that</p> <p>16 for you when I describe what I did.</p> <p>17 Q. Okay. You just referenced the</p> <p>18 fact that your system can be found in the</p> <p>19 Canadian document.</p> <p>20 You agree that the Canadian</p> <p>21 analysis was actually published or produced</p> <p>22 after you had completed your report in the</p> <p>23 MDL, correct?</p> <p>24 MS. PARFITT: Objection. Form.</p> <p>25 THE WITNESS: Certainly it was</p>	<p>1 And then also the question --</p> <p>2 when you're looking at a specific</p> <p>3 question, you may pull in -- like you</p> <p>4 asked me about the starch particle.</p> <p>5 You may pull in things that you give</p> <p>6 less weight because obviously that's</p> <p>7 not just talc, that's starch, and you</p> <p>8 have to consider that. So that is</p> <p>9 part of the process.</p> <p>10 QUESTIONS BY MS. BRANSCOME:</p> <p>11 Q. Dr. Plunkett, the question I</p> <p>12 asked you simply was: The paper that you</p> <p>13 reference that contains some detail about the</p> <p>14 Canadian analysis, that was published after</p> <p>15 you completed your report that's marked here</p> <p>16 as Exhibit 4; is that correct?</p> <p>17 MR. MEADOWS: Objection.</p> <p>18 THE WITNESS: Yes, and I</p> <p>19 believe I answered that at the start.</p> <p>20 I usually try to answer your question,</p> <p>21 and then I try to explain further some</p> <p>22 details I think are important context</p> <p>23 on my answer.</p> <p>24 QUESTIONS BY MS. BRANSCOME:</p> <p>25 Q. I understand that,</p>

24 (Pages 90 to 93)

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Page 94	Page 96
<p>1 Dr. Plunkett. You have given many 2 depositions. You understand I can ask you 3 for more detail if that would be helpful to 4 me. 5 If you could, just focus on the 6 question that I asked, and we can explore 7 additional areas if that's something I'm 8 interested in doing. 9 Okay? 10 MR. MEADOWS: Objection. 11 She's -- 12 MS. BOCKUS: Break? 13 MR. MEADOWS: After I finish my 14 objection. 15 She's going to answer the 16 question as thoroughly as she feels 17 like she needs to answer the question 18 based on the way you ask it. 19 Want to take a break now? 20 MS. BRANSCOME: We can go off 21 the record. 22 VIDEOGRAPHER: We're going off 23 the record at 10:41 a.m. 24 (Off the record at 10:41 a.m.) 25 VIDEOGRAPHER: We are back on</p>	<p>1 panel; is that correct? 2 A. Yes. 3 Q. And so is it your view that a 4 study or an analysis that reaches a 5 particular conclusion should be assigned 6 little weight if it fails to consider all 7 relevant scientific evidence to the issue 8 that it's evaluating? 9 MS. PARFITT: Objection. 10 THE WITNESS: I think it 11 depends on the situation, but that 12 could be the case, yes. It depends 13 on -- on the -- depends on -- I think 14 it would depend on each case, the 15 question being asked, and what was 16 omitted. But, yes, I think it could. 17 QUESTIONS BY MS. BRANSCOME: 18 Q. Okay. And in this situation 19 you identify -- I believe you claimed that 20 eight human studies were not considered by 21 the CIR 2013 panel; is that correct? 22 A. Let me look at the number, but 23 that sounds about right. Yes. 24 Q. All right. And returning, 25 actually, to your prior answer, you said that</p>
Page 95	Page 97
<p>1 the record at 10:56 a.m. 2 QUESTIONS BY MS. BRANSCOME: 3 Q. All right. Dr. Plunkett, we 4 started talking a little bit about the CIR 5 analysis that was done in 2013. 6 Am I correct you no longer 7 consider that reliable? Is that your 8 opinion? 9 A. Yes. 10 Q. Okay. And you identify in your 11 report marked as Exhibit 4, I believe it's 12 paragraph 56? 13 A. Yes, that's correct. And I 14 think I talked about it later on as well, but 15 definitely I do here. 16 Q. Okay. And in paragraph 56, you 17 state that the CIR panel failed to account 18 for all the studies that informed on the 19 issue of migration of particles such as talc 20 upwards through the reproductive tract. 21 Is that your opinion? 22 A. Yes. 23 Q. Okay. And then you state that 24 because of that you assign, quote, little 25 weight to the conclusions reached by the CIR</p>	<p>1 the failure to consider all relevant 2 scientific evidence on a topic would lead you 3 to assign little weight to a particular 4 conclusion. You said that that could happen. 5 Under what circumstances would 6 you assign a conclusion little weight for 7 failing to consider what you consider to be 8 all relevant pieces of scientific literature? 9 A. Well, I think it depends -- 10 well, the reason I specifically addressed 11 that in this case is because that was -- the 12 conclusions about migration is the main 13 reason why the CIR panel then draws 14 additional conclusions later on. 15 So my issue is, migration was 16 key to what -- the decisions they made about 17 the safety issues of talc. And so in that 18 particular case, this -- this failure to 19 consider all the evidence was extremely 20 important, in my view, and I gave it little 21 weight. 22 There might be a situation 23 where some -- for example, you may only look 24 at six or eight studies, even though there 25 may be dozens out there. You may have a</p>

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Page 98	Page 100
<p>1 reason for why you only looked at six or 2 eight, or it may be -- and as a result you 3 may lay that out and, therefore, you may 4 still give weight to conclusions drawn. Or 5 it may be that the six or eight are -- 6 studies that you discuss are not -- the 7 weight is not affected by what you've 8 omitted.</p> <p>9 I believe that the weight is 10 affected by what is omitted when you look at 11 some of the articles being review articles, 12 which give you an understanding of what was 13 generally accepted within the scientific 14 community when you get to reviews, those 15 kinds of things. So it really is a 16 case-by-case basis.</p> <p>17 But certainly I do believe that 18 it is possible that in another circumstance 19 where things are omitted you would come to 20 the same conclusion, that you give those 21 conclusions less weight.</p> <p>22 Q. Is there a way, if someone were 23 try to replicate the weighting of particular 24 evidence based upon your process, for them to 25 know whether or not the omission of a</p>	<p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Okay. Of the eight studies 3 that you identify on page 37 of your report 4 that you contend the CIR panel did not 5 account for, do any of those eight studies 6 specifically discuss the migration of talc in 7 human subjects? 8 A. No, I don't believe they do, 9 but there are a couple of these studies that 10 I found to be extremely important if you want 11 me to explain that to you. 12 Q. Do you break out in your report 13 in any other paragraphs which of these eight 14 articles you consider to be extremely 15 important? 16 And if you could just point me 17 to paragraph numbers, that's good enough if 18 you have, in fact, broken them out. 19 A. I have. I -- this whole 20 section I break -- I talk about each one 21 individually. So I think you can tell by 22 what I read -- what I'm discussing what I 23 thought was important and informative about 24 each of those. 25 Q. Do you rank the eight studies</p>
Page 99	Page 101
<p>1 citation of certain studies means that a 2 study should be given little weight or 3 whether it wouldn't affect the weighting of 4 that scientific article?</p> <p>5 MS. PARFITT: Objection. Form. 6 THE WITNESS: So I think this 7 is the issue of judgment, training and 8 experiencing that is applied to all 9 such assessments, and this is why 10 different scientists may come to 11 different conclusions. But certainly 12 it is -- it was important to my 13 assessment on this issue because of 14 the prominent role that the CIR report 15 gives to their conclusions here for 16 why they then drew conclusions about 17 safety. And so that link was 18 extremely important.</p> <p>19 MS. BRANSCOME: Can we pause 20 for just a moment? 21 VIDEOGRAPHER: We are going off 22 the record at 11:00 a.m. 23 (Off the record at 11:00 a.m.) 24 VIDEOGRAPHER: We are back on 25 the record at 11:01 a.m.</p>	<p>1 in any way by their importance to you? 2 A. Not with any numerical rank, 3 no, but certainly I think I do that for you 4 when I talk about the studies. I give you an 5 understanding of ones that I think are 6 particularly informative and ones that are 7 not.</p> <p>8 So, for example, I weight the 9 human data -- I think I tell you that -- more 10 than the animal data because of the 11 differences between the reproductive tracts 12 of humans versus animals generally, upright 13 versus -- upright and habits and things that 14 humans do that relate to insertions in and 15 out of the reproductive tract, I guess is a 16 nice way to describe it, versus an animal, 17 that those can have, and then also the 18 differences between animals and humans in 19 terms of bursal sac around the ovary, those 20 kinds of things.</p> <p>21 So I do -- that -- I guess that 22 ranking I do give you here. I tell you that 23 I think these -- I think that the most 24 relevant are going to be the human studies 25 versus the animal studies.</p>

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Page 102	Page 104
<p>1 Q. Right.</p> <p>2 So my question specifically is,</p> <p>3 where would you point me to in your report to</p> <p>4 understand the weight that you gave each of</p> <p>5 these particular eight studies?</p> <p>6 A. At my descriptions of those</p> <p>7 studies and what I describe. That's all I</p> <p>8 can tell you.</p> <p>9 Q. And I'm just asking,</p> <p>10 Dr. Plunkett, can you point me in the report</p> <p>11 to where that discussion takes place?</p> <p>12 A. It takes place -- I have a</p> <p>13 discussion for each study, and I would -- and</p> <p>14 if you read what I say about each study, I</p> <p>15 try to go through what the strengths and</p> <p>16 weaknesses of those studies are.</p> <p>17 And so those -- that would be,</p> <p>18 let's see -- you want me to give you the</p> <p>19 starting paragraph?</p> <p>20 Q. So, for example, Parmley and</p> <p>21 Woodruff. Can you point me to where in your</p> <p>22 report you discuss Parmley and Woodruff, such</p> <p>23 that I can understand the weight that you</p> <p>24 gave that particular study?</p> <p>25 A. So the year of it is...</p>	<p>1 So what I do is, when I'm</p> <p>2 discussing about these -- all of these papers</p> <p>3 here contribute to my weight of the evidence.</p> <p>4 And if it's a human study, I'm giving those</p> <p>5 more weight than I'm giving animal studies.</p> <p>6 And that's described.</p> <p>7 And then within papers I'm</p> <p>8 pulling out information that contributes to</p> <p>9 what I think is important about what the</p> <p>10 study says, and that -- and the importance of</p> <p>11 what is described within the study</p> <p>12 contributes to my weight.</p> <p>13 And I don't know how else to</p> <p>14 describe it to you. That is the process that</p> <p>15 scientists go through when they evaluate</p> <p>16 data.</p> <p>17 Q. And so my question to you:</p> <p>18 Earlier you said of these eight studies, some</p> <p>19 of them were particularly important to you.</p> <p>20 How would I, using only what's</p> <p>21 written in your report, understand which of</p> <p>22 those eight studies was of particular</p> <p>23 importance to you?</p> <p>24 A. So it would have to do with</p> <p>25 what I discuss about the study. So I'm</p>
Page 103	Page 105
<p>1 So I think I discuss it in</p> <p>2 paragraph 44, and so I describe for you what</p> <p>3 important information is in there, which is</p> <p>4 the information that I take as forming part</p> <p>5 of my weight of the evidence.</p> <p>6 So one of the most important</p> <p>7 things is what -- they have a figure they</p> <p>8 show, and they're showing -- which is one of</p> <p>9 the unique figures in all of the published</p> <p>10 literature. But it talks about the</p> <p>11 differences between the female reproductive</p> <p>12 tract and the male reproductive tract, and it</p> <p>13 shows the actual -- it talks about a</p> <p>14 discussion of movement from substance in the</p> <p>15 environment through -- into the vagina, into</p> <p>16 the fallopian tubes. So it's a paper that</p> <p>17 addresses that very specific issue.</p> <p>18 Q. So my question to you, though,</p> <p>19 is, where do you have a discussion of the</p> <p>20 weight that you give to these particular</p> <p>21 articles?</p> <p>22 A. So the discussion of the weight</p> <p>23 has to do with the information described. I</p> <p>24 don't give them a numerical ranking. I told</p> <p>25 you that.</p>	<p>1 telling you, when I -- if you look through</p> <p>2 this entire section, this is the Parmley and</p> <p>3 Woodruff paper. It is important because it</p> <p>4 addresses the specific issue of movement of</p> <p>5 environmental substances from the outside to</p> <p>6 the inside. So I'm giving that importance in</p> <p>7 my evaluation because of what that author is</p> <p>8 actually discussing.</p> <p>9 I don't know how else to</p> <p>10 describe that. I apologize. I mean, to me,</p> <p>11 weight of the evidence is a process that</p> <p>12 scientists use bringing their training and</p> <p>13 experience and judgment, and it's not a</p> <p>14 numerical process across the board, it just</p> <p>15 is not, based on the way weight of the</p> <p>16 evidence is used within science.</p> <p>17 Q. Now, Dr. Plunkett, though, you</p> <p>18 would acknowledge that if you wanted to</p> <p>19 assign numerical values to the studies, that</p> <p>20 has been something that has been done by</p> <p>21 other authors and other authors on whom you</p> <p>22 rely, correct?</p> <p>23 MS. PARFITT: Objection. Form.</p> <p>24 THE WITNESS: I don't believe</p> <p>25 that's true. I'll need to look -- I</p>

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Page 106	Page 108
<p>1 don't believe that's true with respect 2 to the biological information. I 3 believe it may be true with respect to 4 the epidemiology studies. 5 You want me to look real quick 6 to confirm that? I can do that really 7 quick, but... 8 QUESTIONS BY MS. BRANSCOME: 9 Q. I'm simply saying, could you 10 assign a numerical value if you chose to do 11 so? 12 MR. MEADOWS: Objection. 13 Objection. Form. 14 THE WITNESS: And I'm -- what 15 I'm trying to say to you is I think 16 that I -- that there is no one set of 17 rules that you would assign in order 18 to do that for all the types of 19 studies that you weigh. 20 I would agree that I have seen 21 it routinely done -- well, not 22 routinely, but I've seen it done 23 within the epidemiological community 24 when they go through the epi data. 25 But not -- it's not something that</p>	<p>1 Q. All right. And you are aware 2 that there is, in fact -- called PDQs, 3 correct? 4 A. That's the abbreviation, yes. 5 Q. Right. And you're aware that 6 the National Cancer Institute has in fact 7 published a PDQ that addresses a potential 8 connection between talc and ovarian cancer, 9 correct? 10 A. I'm aware of several that have 11 been done over the years, but, yes, I'm aware 12 of that. 13 Q. And have you reviewed those? 14 A. Yes, I have. 15 Q. Are they listed on your 16 reliance list? 17 A. No, but they're listed within 18 the materials as discussed within my 19 depositions, and I thought -- and my 20 testimony. I thought that was part of my 21 reliance list. I believe that it -- it was 22 in my reliance list, is encompassing all of 23 the testimony as well as the actual 24 documents. Maybe I'm mistaken, but that was 25 my understanding.</p>
Page 107	Page 109
<p>1 I've seen done when you talk about 2 weight of the evidence as part of a 3 human health risk assessment. That is 4 not something that scientists 5 typically do as far as giving 6 numerical rankings. 7 QUESTIONS BY MS. BRANSCOME: 8 Q. You're familiar with the 9 National Cancer Institute, correct? 10 A. Yes, I am. 11 Q. All right. They are considered 12 to be the nation's leader in cancer research, 13 correct? 14 MS. PARFITT: Objection to 15 form. 16 THE WITNESS: The National 17 Cancer Institute? 18 Yes, they are. I don't know if 19 they're "the" leading, but they're one 20 of the leading, that's true. 21 QUESTIONS BY MS. BRANSCOME: 22 Q. Okay. And you're familiar with 23 publications that they issue called physician 24 data queries? 25 A. Yes, I am.</p>	<p>1 Q. Okay. If they are not on your 2 reliance list, should they be? 3 A. I believe that they are on my 4 reliance list by it having been pointed to as 5 part of the testimony that I have given and 6 the documents that I have relied upon during 7 testimony. 8 Q. Okay. And you are aware that 9 they have issued a PDQ that -- on the website 10 as of today, correct? 11 A. I haven't looked today, so I'm 12 sure -- but I know that -- I don't believe it 13 has been removed, so I believe that there is 14 something there, yes. 15 Q. All right. And what is your 16 understanding of the position stated in the 17 PDQ with respect to a possible link between 18 talc and ovarian cancer? 19 A. So I'd have to look at the one 20 today to tell you what it says, but it's 21 evolved over time and it's changed over time, 22 and I have specific opinions that I've 23 expressed at trial about that issue. 24 Do you want me to go into that 25 details or I mean --</p>

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Page 110	Page 112
<p>1 Q. I'm not asking about your 2 opinions about what their position is. I'm 3 simply asking you, Dr. Plunkett, the most 4 recent NCI PDQ that you have reviewed, what 5 is the position that the National Cancer 6 Institute has taken with respect to the 7 relationship between talc and ovarian cancer? 8 A. So I would want to pull it out 9 to give you the specific statement of their 10 position, but their position has changed such 11 that later in time they've weakened the 12 link -- their statements about the link 13 between ovarian cancer and genital talc use. 14 So it used to be seen as a 15 cause, and now I believe it's not seen as a 16 cause. I don't know the exact language, 17 though. I'd have to look at it as -- maybe 18 risk factor is the better word to use. 19 And I need to look at the most 20 recent one. And that would be the best way. 21 Let's just see what it says. 22 Q. Okay. 'Cause is it your 23 position as you sit here today that the 24 National Cancer Institute has ever issued a 25 statement that talc causes ovarian cancer?</p>	<p>1 any -- whatever portion of this is helpful to 2 you. 3 And then if you could answer my 4 question, Dr. Plunkett, of what is the 5 position as stated in Deposition Exhibit 6 Number 7 of the National Cancer Institute 7 with respect to the relationship between talc 8 and ovarian cancer? 9 A. So I would be looking at the 10 section on page 12 of 18, and maybe you're 11 looking somewhere else, but that's where they 12 actually talk about perineal talc exposure. 13 And it's under the section where they have 14 now moved into factors with an adequate 15 evidence of an association and they describe 16 it here. So they're calling it an 17 association where the weight of the evidence 18 is not adequate to support that association. 19 Q. All right. And so the first 20 sentence of the section under perineal talc 21 exposure states, "The weight of the evidence 22 does not support an association between 23 perineal talc exposure and an increased risk 24 of ovarian cancer." 25 Did I read that correctly?</p>
Page 111	Page 113
<p>1 A. I believe it was listed as a 2 risk factor for ovarian cancer in the older 3 PDQs. 4 (Plunkett Exhibit 7 marked for 5 identification.) 6 QUESTIONS BY MS. BRANSCOME: 7 Q. I do have a copy here. Just 8 for the sake of the record, we will mark this 9 as Plunkett Deposition Exhibit Number 7. 10 Handing a copy to you, 11 Dr. Plunkett, do you recognize the document 12 that I just handed you that's marked as 13 Exhibit 7? 14 MR. LOCKE: What's the date of 15 that? 16 MS. BRANSCOME: This was 17 printed on December 14, 2018. 18 THE WITNESS: It's -- the 19 updated date is June 22, 2018, if that 20 helps. 21 MR. LOCKE: Yes, thank you. 22 THE WITNESS: I have seen this 23 one, yes. 24 QUESTIONS BY MS. BRANSCOME: 25 Q. All right. And you can review</p>	<p>1 A. You did read that correctly. 2 Q. All right. And it indicates 3 that "results from case-control and cohort 4 studies are inconsistent." 5 Did I read that correctly, 6 Dr. Plunkett? 7 A. You did. 8 Q. And the question that I would 9 ask simply is, do you discuss the National 10 Cancer Institute PDQ in the report that 11 you've issued in the MDL, which is identified 12 as Exhibit 4? 13 A. I don't specifically discuss 14 this document, no, I do not. 15 Q. Okay. And you understand that 16 the NCI PDQ did a weight of the evidence 17 analysis that followed a formal evidence 18 ranking system, correct? 19 MS. PARFITT: Objection. 20 THE WITNESS: So I -- it's not 21 laid out here, but they do have a 22 process they use. 23 Is that what you're asking me? 24 QUESTIONS BY MS. BRANSCOME: 25 Q. Yes.</p>

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Page 114	Page 116
<p>1 A. Yes. And again, they're</p> <p>2 ranking the epidemiological data, and so I</p> <p>3 understand that that is there, yes.</p> <p>4 Q. Now, you've said a few times</p> <p>5 that you could qualitative -- you could give</p> <p>6 a quantitative weight to an epidemiological</p> <p>7 study, somehow suggesting that it is</p> <p>8 different from other types of studies.</p> <p>9 What is it about a</p> <p>10 toxicological study, for example, that would</p> <p>11 prevent someone from giving a quantitative</p> <p>12 weight in a weight of the evidence analysis?</p> <p>13 A. Because it is just what is</p> <p>14 typically done and not done. There are</p> <p>15 certain practices within the community, what</p> <p>16 is kind of -- I would say that scientists use</p> <p>17 routinely, or scientists have used. Not all</p> <p>18 scientists give numerical rankings to</p> <p>19 epidemiological data either, because even</p> <p>20 within a Bradford Hill assessment, when you</p> <p>21 use the considerations, there's no</p> <p>22 requirement for ranking studies in order to</p> <p>23 meet the requirements of use of that</p> <p>24 methodology.</p> <p>25 Q. Okay.</p>	<p>1 of epidemiological evidence?</p> <p>2 A. If by -- you mean prevent, was</p> <p>3 someone stopping me from doing that, no. But</p> <p>4 if you ask what would be standard practice</p> <p>5 based on my experience, I would not be doing</p> <p>6 that.</p> <p>7 Q. Has anyone -- and I'm not</p> <p>8 referring in this case to any attorneys. But</p> <p>9 has anyone reviewed your -- the weighting</p> <p>10 that you gave specific pieces of evidence as</p> <p>11 essentially a form of a peer review process?</p> <p>12 A. If by that you mean have I</p> <p>13 submitted my opinions for publication, no, I</p> <p>14 have not done that. Part of -- that's partly</p> <p>15 driven by my understanding of the evidence</p> <p>16 that I reviewed, that some of it may not be</p> <p>17 something that I should be discussing</p> <p>18 necessarily in a public form outside of the</p> <p>19 cases I'm working in.</p> <p>20 But certainly I have not</p> <p>21 submitted it for publication, if that's what</p> <p>22 you mean. No, I have not done that.</p> <p>23 Q. Okay. Has the methodology that</p> <p>24 you have used in the MDL, has that been --</p> <p>25 have you submitted any type of analysis using</p>
Page 115	Page 117
<p>1 A. But I have seen it done in the</p> <p>2 epidemiology community, and that is the most</p> <p>3 common place I see it. I do not see other</p> <p>4 toxicologists that are assessing animal</p> <p>5 studies and in vitro studies doing it that</p> <p>6 same way.</p> <p>7 When you do a human health risk</p> <p>8 assessment, that isn't routine practice to do</p> <p>9 numerical rankings on studies.</p> <p>10 Q. Okay.</p> <p>11 A. At least in my experience and</p> <p>12 in my training, and I was trained in the use</p> <p>13 of risk assessment by one of the individuals</p> <p>14 who actually invented the process.</p> <p>15 Q. Okay. Okay. But do you</p> <p>16 consider the epidemiological evidence as part</p> <p>17 of your risk assessment in the MDL?</p> <p>18 A. I do, because I'm looking at it</p> <p>19 in the context of what is out there and</p> <p>20 what's available. I don't always have human</p> <p>21 data when I do risk assessments, but in this</p> <p>22 one I do. So I do consider them, yes.</p> <p>23 Q. Okay. Did anything prevent you</p> <p>24 from doing a quantitative assessment of the</p> <p>25 weight that you were giving different pieces</p>	<p>1 that methodology for publication even outside</p> <p>2 of particularly looking at Johnson's baby</p> <p>3 powder, for example?</p> <p>4 A. Yes, in -- if you look at my</p> <p>5 publications that describe risk assessments</p> <p>6 that I have done. So the one that would come</p> <p>7 to -- to play that's similar as far as the</p> <p>8 scope of the weight of the evidence would --</p> <p>9 at least with the animal and the in vitro</p> <p>10 studies, would be the paper that I published</p> <p>11 on copper, looking at the database of copper</p> <p>12 and identifying points of departure and</p> <p>13 target organs and risk -- risk issues based</p> <p>14 on copper use in humans, trying to set a --</p> <p>15 understand what a safe exposure level could</p> <p>16 be to copper in water. And that was</p> <p>17 published -- that actually was one of the</p> <p>18 papers that's published with Dr. Krewski, who</p> <p>19 is one of the authors of this risk assessment</p> <p>20 in Canada.</p> <p>21 Q. And is it your position that</p> <p>22 you follow the same methodology in what</p> <p>23 you've reported in the MDL with respect to</p> <p>24 Johnson's baby powder that you did in your</p> <p>25 analysis of copper?</p>

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Page 118	Page 120
<p>1 A. Yes, with the process of going 2 through all of the publicly available 3 information, putting it together based on its 4 relevancy and reliability. 5 We did a process where we 6 grouped it based on animal versus human, just 7 like I've done here. And we call it the 8 bins, but it's the same idea. I have a bin 9 of human data, I have a bin of animal data 10 and a bin of in vitro data. And so, yes, the 11 process was very, very similar. 12 Q. Okay. Returning back to some 13 documents that you chose not to cite in your 14 report, you do not discuss the Gonzales 2016 15 study in your report for the MDL, correct? 16 MS. PARFITT: Objection. Form. 17 THE WITNESS: I'll have to 18 look. It is not cited in the 19 reference list to my report, that is 20 true. So that means it would not be 21 mentioned specifically in the body of 22 the report. 23 QUESTIONS BY MS. BRANSCOME: 24 Q. You're familiar with the 25 Gonzalez 2016 study, correct?</p>	<p>1 include something like the Gonzales 2016 2 study, but yet you will disagree the 3 2013 -- the CIR 2013, you will give it little 4 weight for not discussing particular studies? 5 A. So that's a very different 6 exercise. You want me to explain my thinking 7 on that? I can do that for you, but I 8 believe that's apples and oranges question. 9 My reasons for giving little 10 weight to the CIR overall assessment versus 11 my weight or the assessment I make of an 12 individual piece of data, that's different. 13 And that's what you're describing for me. 14 And I believe Gonzales is in my 15 overall reliance list, so I have read 16 Gonzales. It is something that I have 17 considered; it's not something that I've 18 cited in my paragraphs. So it doesn't mean 19 it didn't go into my weight of the evidence, 20 because I do have it and I have reviewed it. 21 I just don't recall the details on it. 22 Q. Is it your position as you sit 23 here today that you know for sure that the 24 CIR panel did not -- was not aware of or even 25 considered any of the eight studies that you</p>
Page 119	Page 121
<p>1 A. If you want me to talk about 2 it, you'd have to pull it out for me, but I 3 know the name, yes. 4 Q. Okay. And it was looking at an 5 association between the perineal use of talc 6 and ovarian cancer, correct? 7 A. That, I'd have to look at it to 8 tell you. I believe it was a human study 9 that would be consistent with that, but I 10 need to pull it out to look at it. 11 Q. All right. Do you, as you sit 12 here today, do you know why you did not 13 discuss it in your report? 14 A. I wasn't doing a full causation 15 analysis in this report, so as a result I'm 16 not trying to characterize every piece of 17 human data. But I certainly am looking at 18 the consistency across the studies, and 19 that's what I've done. 20 And I mention it here. I do 21 think I mention here that there are studies 22 that came to different conclusions than the 23 ones that I'm specifically describing. 24 Q. Okay. And so why is it that -- 25 why is it acceptable for you to choose not to</p>	<p>1 contend the omission of which makes it of 2 little weight? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: I would say I'm 5 99.9 percent sure, based on the 6 process that is -- that goes in. And 7 if you want me to explain, I'll tell 8 you why I feel that level of surety. 9 You know, I can always say that 10 maybe there was someone that came to 11 the panel that did a search on their 12 own, but that is not what's done. The 13 individuals that come to the panel are 14 given a body of information provided 15 to them in written form that they 16 review. So it's not like they -- they 17 have access to anything that isn't 18 cited in the actual report. 19 QUESTIONS BY MS. BRANSCOME: 20 Q. Okay. The eight articles that 21 you discuss that are not mentioned in the CIR 22 panel's work, they are publicly available 23 pieces of scientific literature, correct? 24 A. Yes, which was why it's 25 interesting to me that those were not grabbed</p>

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Page 122	Page 124
<p>1 and included within -- within the assessment 2 done by the -- by the PCPC's group that 3 handles CIR -- handled the CIR process here. 4 Q. Okay. We received just before 5 your deposition, a few days in advance, a 6 list of materials that have been added to 7 your reliance list since you produced your 8 report in this case. 9 Did you provide that list of 10 materials to counsel to -- are you aware of 11 the materials that were identified? 12 A. Yes, I am. They're ones that I 13 have reviewed since my report and -- yes, 14 which would have been, I believed, important 15 for you to know about, because obviously you 16 wouldn't know if I hadn't provided that to 17 you, and fair game for you to ask me about. 18 Q. On that list was contained a 19 number of news articles. 20 A. Uh-huh. 21 Q. Are news articles pieces of 22 scientific information that you typically 23 consider in performing a risk assessment? 24 A. No, they're not part of my risk 25 assessment, but they -- but they were</p>	<p>1 section on the role of the industry in 2 Section 7. 3 Q. Okay. So the newspaper 4 articles are not something that you are 5 considering as part of your analysis of 6 whether there is a risk of ovarian cancer 7 from Johnson's baby powder, correct? 8 A. No, that's a separate issue 9 because it's not -- it's not scientific data, 10 per se. 11 Q. Okay. All right. Now, if you 12 could turn to paragraph 31 in your report. 13 Okay. You discuss the 14 biological effects of talc in this paragraph 15 and in others, correct? 16 A. Yes, I would call this my 17 introductory paragraph to transition into a 18 specific topic, yes. 19 Q. Okay. And you talk here about 20 the structure and size of talc affecting its 21 properties. 22 What do you mean by that? 23 A. So whether it's fibrous enough, 24 platy, fibrous. Whether it is particle sizes 25 of less than 10 microns, less than 5 microns,</p>
Page 123	Page 125
<p>1 relevant to -- they were relevant to my 2 overall assessment of the issue of what the 3 company is doing with regard to public 4 dissemination of information. 5 So it's not the risk assessment 6 part. It's more on the issue of the -- when 7 I talk about the different influences of the 8 company on public dissemination of 9 information, I went through the different 10 specific issues. So this would be a specific 11 issue related to a news report that someone 12 comes out with, the Reuters report, and then 13 looking at what the company is saying in 14 addition to that. 15 So it's understanding -- for 16 example, the documents that Reuters 17 discusses, many of those I'm sure I have 18 seen, although I don't have access to -- I 19 wasn't able to go on websites and download 20 everything that they cite. But certainly 21 they looked familiar, some of the ones I did 22 see. 23 So it's that issue of -- the 24 last part of my report, I think. Want me to 25 tell you the section? It would be in the</p>	<p>1 greater than 75 microns. There's 2 different -- certain pieces of literature 3 deal with different size ranges of talc. The 4 smaller the size range, the more toxic it is, 5 for example, to lung tissue; the more likely 6 it is to be able to move, based upon the 7 size, versus being engulfed by a macrophage 8 if it's a larger particle, things like that. 9 Q. So focusing specifically on 10 ovarian cancer, what role does size and 11 structure of a talc particle play with 12 respect to a risk of ovarian cancer in your 13 opinion? 14 A. I don't think I formed a 15 opinion that it has to be a specific size or 16 structure, because the -- my opinions are 17 related to the fact that we have a complex 18 mixture of ingredients within the body 19 powder, and my assessment's been on the 20 overall consumer product, not on any one 21 particular ingredient only within it. 22 So it's the idea of just 23 understanding that size and structure of 24 these particles are general principles that 25 affect toxicology. So a larger particle or a</p>

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Page 126	Page 128
<p>1 fibrous particle may have a different tissue 2 toxicity response than a smaller particle. 3 So in other words -- I think I 4 discuss this later in a paragraph about 5 pleurodesis, the idea that you can get acute 6 versus chronic inflammation, or respiratory 7 distress or not. So it's just this idea of a 8 general principle that outlines how you would 9 think about particles generally as a 10 toxicologist. 11 Q. Well, okay. So you said that 12 your assessment is based on the overall 13 consumer product. That would be Johnson's 14 baby powder or SHOWER TO SHOWER®, correct? 15 A. Yes. 16 Q. All right. 17 A. Or Shimmer. I think that's the 18 other name. There's a third product. 19 Q. Okay. But my question to you 20 is, you actually cite a number of pieces of 21 literature in the section about the alleged 22 toxicity of talc that don't relate to the 23 overall consumer products at issue in this 24 case, correct? 25 MS. PARFITT: Objection. Form.</p>	<p>1 known to affect tissue toxicity as far as 2 adverse events like inflammation and/or 3 irritation. 4 Q. Okay. So that's -- that's what 5 I'm trying to understand in more detail. 6 What is your opinion with 7 respect to -- let's take size to start with. 8 Is there a particular size talc particle that 9 is more or less likely to cause inflammation, 10 in your opinion? 11 A. It depends whether you're 12 talking about acute or chronic. I would say 13 for acute inflammation the larger particles, 14 such as some of the particle sizes that are 15 used in the pleurodesis products, are more 16 likely to initiate an acute inflammatory 17 response due to the fact that they're large 18 enough that the body will recognize them with 19 a fairly robust foreign body response. 20 Q. What is your definition of 21 large? 22 A. So the literature varies, but 23 certainly particles that are above -- some of 24 the literature talks about particles that are 25 in the range of 25 to 75. Some of them talk</p>
Page 127	Page 129
<p>1 THE WITNESS: No, I would 2 disagree with that when you use the 3 word "relate." Relate to me means is 4 it relevant to the assessment, and 5 they are, even if they're not just on 6 the finished product. 7 But if what you mean is that 8 there are studies that did not test 9 the consumer product but individual 10 ingredients or -- that is true, yes, 11 but all of that is relevant or relates 12 to the overall risk assessment. 13 QUESTIONS BY MS. BRANSCOME: 14 Q. Okay. So given your view that 15 information about the individual constituents 16 is relevant to evaluating the overall 17 toxicity of the ultimate consumer products, 18 then my question to you is: How does the 19 structure and size of the component talc 20 particles play a role in toxicity with 21 respect to ovarian cancer? 22 A. Just generally -- it's not 23 just -- well, with respect to ovarian cancer, 24 we start with irritation, inflammation 25 potential. Size of particles and shape are</p>	<p>1 about larger particles even than that. 2 It has to do with the fact 3 that -- this is complicated by the fact that 4 any consumer product -- or any talc sample 5 will have a range of sizes because they don't 6 select for one size. They select for smaller 7 than. So a 200 mesh, a 400 mesh, that has do 8 with what will filter through. 9 So pleurodesis, they try to 10 avoid for those products the really small -- 11 large amounts of less than 10 because that 12 leads to respiratory distress, whereas many 13 of the consumer talc products are using much 14 smaller, finer particles to get that feel and 15 performance they want from the consumer body 16 powders. 17 Q. Have you reviewed -- focusing 18 specific on Johnson & Johnson's products, 19 have you reviewed the documents that relate 20 to the specifications for the Johnson's 21 products with respect to the size of the 22 plate particles? 23 A. I have seen those, yes. I 24 can't tell you what each of them says without 25 pulling them out, but, yes, that is certainly</p>

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Page 130	Page 132
<p>1 documents I have seen and relied upon.</p> <p>2 Q. Is it consistent with your</p> <p>3 understanding that it was Johnson & Johnson's</p> <p>4 intention to select large platy talc</p> <p>5 particles for its products?</p> <p>6 MS. PARFITT: Objection to</p> <p>7 form.</p> <p>8 QUESTIONS BY MS. BRANSCOME:</p> <p>9 Q. Have you seen that in the</p> <p>10 documents?</p> <p>11 A. I don't know that it's</p> <p>12 described quite that way, but they certainly</p> <p>13 were doing a 200 mesh selection. So -- for</p> <p>14 their body powders products. So -- and they</p> <p>15 were trying -- and they did make attempts to</p> <p>16 look for sources that were more platy talc</p> <p>17 than other forms, but that doesn't ensure</p> <p>18 that everything is platy talc.</p> <p>19 Q. Are you familiar with the term</p> <p>20 "fines"?</p> <p>21 A. Yes, generally, but I'm not --</p> <p>22 but I'm not an expert in the processing of</p> <p>23 talc as far as how you would go about</p> <p>24 choosing an ore or a mine. There's others</p> <p>25 that will be addressing that. That's not my</p>	<p>1 effects that beneficiation can have on the</p> <p>2 level of the component -- the components in</p> <p>3 talc and what ultimately ends up in one of</p> <p>4 Johnson & Johnson's consumer products?</p> <p>5 MR. MEADOWS: Objection.</p> <p>6 THE WITNESS: So I'm not -- I'm</p> <p>7 not familiar with all the details, but</p> <p>8 I am familiar that it is a process</p> <p>9 they're using to attempt to result in</p> <p>10 a product that has characteristics</p> <p>11 that would be desirable for a consumer</p> <p>12 product.</p> <p>13 Again, there is my</p> <p>14 understanding that others are going to</p> <p>15 be discussing the geology or the</p> <p>16 processing, and that is not something</p> <p>17 I'm looking at.</p> <p>18 The literature as it relates to</p> <p>19 what has been tested in the public</p> <p>20 literature in particular, and that</p> <p>21 would be either an ingredient or a --</p> <p>22 or a consumer product or a -- they may</p> <p>23 discuss exposure occupationally to</p> <p>24 mining or milling, which is -- which</p> <p>25 is an issue that you can consider when</p>
Page 131	Page 133
<p>1 area.</p> <p>2 Q. What is your understanding of</p> <p>3 the term "fines"?</p> <p>4 A. My understanding of the term</p> <p>5 "fines" has to be looking for a sample or a</p> <p>6 group that has been processed such that it</p> <p>7 has certain characteristics.</p> <p>8 Other than that, I would refer</p> <p>9 you to the individuals in litigation that are</p> <p>10 going to be dealing with the processing.</p> <p>11 Q. Okay. Have you taken into</p> <p>12 account in your analysis in any way the</p> <p>13 beneficiation process that occurs between the</p> <p>14 time that the talc is mined and it ends up in</p> <p>15 one of the consumer products that is relevant</p> <p>16 to your analysis?</p> <p>17 MR. MEADOWS: Objection.</p> <p>18 THE WITNESS: So what do you</p> <p>19 mean by taking it into account? Am I</p> <p>20 aware that they have something that's</p> <p>21 in place for that? Yes.</p> <p>22 But take into account, what do</p> <p>23 you mean by that?</p> <p>24 QUESTIONS BY MS. BRANSCOME:</p> <p>25 Q. Are you familiar with the</p>	<p>1 you're reviewing that literature as</p> <p>2 well.</p> <p>3 QUESTIONS BY MS. BRANSCOME:</p> <p>4 Q. Okay. And so when you cite --</p> <p>5 for example, you have a significant number</p> <p>6 of -- I'm trying to find the right paragraph.</p> <p>7 You have a section in your</p> <p>8 report where you discuss a number of</p> <p>9 different articles that relate to talc, and</p> <p>10 in parentheses you identify that the talc</p> <p>11 source might be cosmetic, it might be</p> <p>12 industrial, things of that nature, correct?</p> <p>13 A. Yes, I do that on purpose</p> <p>14 because I wanted -- I did look at the</p> <p>15 literature to understand what they were --</p> <p>16 what they were -- what type of exposure they</p> <p>17 were describing.</p> <p>18 Q. Okay. And so understanding</p> <p>19 that some of those products are not</p> <p>20 representative of what ultimately is in</p> <p>21 Johnson's baby powder, do you have anything</p> <p>22 in your report that explains how you did or</p> <p>23 did not give weight to those particular</p> <p>24 studies?</p> <p>25 MS. PARFITT: Objection. Form.</p>

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<p style="text-align: right;">Page 134</p> <p>1 THE WITNESS: Let me look and 2 see what I say. 3 If the question has to do with 4 numerical rankings, no, I did not do 5 that. But you're asking something 6 else, right, broader than that, 7 correct? 8 QUESTIONS BY MS. BRANSCOME: 9 Q. The question that I have is, 10 how did -- is there somewhere in this report 11 that I can understand the weight that you 12 assigned to say a study that related to 13 industrial talc as opposed to information 14 about cosmetic talc, for example? 15 MR. MEADOWS: Objection. 16 THE WITNESS: So I -- I'm -- I 17 believe I address that. I don't know 18 it's exactly answering your question, 19 but I lay out for you the 20 characteristics of the literature in 21 paragraph 37, and I point out that the 22 scientific literature varies. 23 And the fact -- and I point -- 24 and I admit -- I'm not admitting. I'm 25 stating the fact that in some cases</p>	<p style="text-align: right;">Page 136</p> <p>1 something that ever ended up in Johnson's 2 products, correct? 3 MR. MEADOWS: Objection. 4 THE WITNESS: I don't think I 5 can answer that yes or no. I haven't 6 done an assessment to see whether it 7 ever ended up in the products. That's 8 a different question. 9 I certainly am aware of the 10 fact that was not a primary source of 11 their talc, that is true. I do know 12 that. 13 In other words, I don't have 14 records from -- going back from 1894 15 on what the source of their talc was. 16 So I can't tell you over time. 17 What I do know, what's been put 18 into depositions and testimony of 19 company employees more recently, where 20 it's my understanding that the 21 principal sources over the years were 22 either the Vermont mine, the Italian 23 mine or the Chinese mine. And there 24 were different interruptions in time 25 where different mines were used,</p>
<p style="text-align: right;">Page 135</p> <p>1 the authors will not describe it 2 specifically as the type of talc, but 3 just talc, whereas -- with no 4 description of purity or state, for 5 example. But in cases where the 6 literature does, I did consider that 7 in my weight of the evidence. 8 So, for example, when I -- when 9 I lay it out here in these bullets 10 where I'm putting for you tremolite 11 mining industrial grade cosmetic, it 12 certainly is something that I weighed. 13 And obviously as much information as I 14 can get on cosmetic-grade talc is 15 going to be most important in the 16 assessment, but that doesn't mean the 17 other information isn't relevant. 18 You want me to explain why? 19 QUESTIONS BY MS. BRANSCOME: 20 Q. Well, so, for example, you 21 describe the Dreessen article that related to 22 trimellitic talc that's mined out of 23 New York. 24 You would agree that 25 trimellitic talc from New York is not</p>	<p style="text-align: right;">Page 137</p> <p>1 depending on sourcing. 2 QUESTIONS BY MS. BRANSCOME: 3 Q. So as part of your expert 4 analysis where you are evaluating articles 5 that relate to different types of talc from 6 different sources of talc, have you done an 7 analysis of how those particular types of 8 talc do or do not relate to what is in the 9 consumer product manufactured by Johnson & 10 Johnson? 11 MS. PARFITT: Objection. Form. 12 THE WITNESS: The first part of 13 your question, again? I'm sorry. 14 MS. BRANSCOME: Would you read 15 it back? 16 THE WITNESS: Could you read it 17 back to me again? I didn't mean to 18 wander, but the first few words I 19 missed. 20 (Court Reporter read back 21 question.) 22 THE WITNESS: Okay. So I 23 certainly did, which is why I'm 24 breaking this out here for you this 25 way.</p>

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<p style="text-align: right;">Page 138</p> <p>1 So I am -- I am certainly</p> <p>2 recognizing, and I analyzed on the</p> <p>3 paper -- through the papers what type</p> <p>4 of product, if available, that the</p> <p>5 data is on.</p> <p>6 But if you read my report in</p> <p>7 the process of risk assessment, all of</p> <p>8 these categories of papers are</p> <p>9 relevant to telling you something</p> <p>10 about what talc can do. And then when</p> <p>11 you talk about drawing final</p> <p>12 conclusions, I'm looking for</p> <p>13 information, if I can, and I have it,</p> <p>14 that is on point to the product that</p> <p>15 was sold.</p> <p>16 So certainly the studies that</p> <p>17 give me information on cosmetic-grade</p> <p>18 talc are extremely important to my</p> <p>19 assessment, and they're ones that I've</p> <p>20 discussed or we've even used in trial</p> <p>21 before when we've talked about putting</p> <p>22 together a timeline.</p> <p>23 That's what this is about, by</p> <p>24 the way. This discussion here, I'm</p> <p>25 starting to lay out what information</p>	<p style="text-align: right;">Page 140</p> <p>1 that to draw conclusions based upon</p> <p>2 what was available for me to assess.</p> <p>3 QUESTIONS BY MS. BRANSCOME:</p> <p>4 Q. Okay.</p> <p>5 A. I don't know how else to answer</p> <p>6 it for you. That's what the section is meant</p> <p>7 to do, and that's why I broke it out that</p> <p>8 way. You know, I recognize that there is</p> <p>9 data on different things.</p> <p>10 What's interesting about even</p> <p>11 the data on different things, there's a</p> <p>12 common mechanism that is involved with the</p> <p>13 type of tissue toxicity you get, and that's</p> <p>14 irritation and inflammation. Regardless of</p> <p>15 whether it is of a certain grade or not, you</p> <p>16 get certain types of adverse reactions. May</p> <p>17 be a more sustained reaction with a</p> <p>18 industrial grade versus cosmetic grade, but</p> <p>19 they all have the capability to produce that</p> <p>20 type of adverse effect.</p> <p>21 Q. Dr. Plunkett, where can you</p> <p>22 point me to in your report that you discuss</p> <p>23 the weight that you give studies that relate</p> <p>24 to talc from New York as opposed to studies</p> <p>25 that relate to cosmetic talc that ultimately</p>
<p style="text-align: right;">Page 139</p> <p>1 was available over time, and that's</p> <p>2 simply what this is. It's a survey of</p> <p>3 the literature that talks about</p> <p>4 adverse effects of talc, and if I can,</p> <p>5 I separate it into different qualities</p> <p>6 or purities.</p> <p>7 QUESTIONS BY MS. BRANSCOME:</p> <p>8 Q. Dr. Plunkett, respectfully, I</p> <p>9 don't believe you answered my question.</p> <p>10 Can you point me to anywhere in</p> <p>11 your expert report that's been produced in</p> <p>12 this MDL where you do an analysis of how the</p> <p>13 different talc types and sources that you are</p> <p>14 citing as support for the toxicity of talc</p> <p>15 generally relate to the products manufactured</p> <p>16 by Johnson & Johnson?</p> <p>17 MR. MEADOWS: Objection.</p> <p>18 THE WITNESS: So I don't know</p> <p>19 how else to answer that but to tell</p> <p>20 you I think that's what this whole</p> <p>21 section is about. I step you</p> <p>22 through -- I identify different types</p> <p>23 of evidence. I identify for you what</p> <p>24 was tested in those different pieces</p> <p>25 of evidence, and then I step through</p>	<p style="text-align: right;">Page 141</p> <p>1 ended up in Johnson's baby powder?</p> <p>2 MS. PARFITT: Objection. Form.</p> <p>3 THE WITNESS: I've tried to</p> <p>4 answer that for you. The weight that</p> <p>5 I'm giving -- the weight that I'm</p> <p>6 giving is part of my assessment. So,</p> <p>7 again, I don't give numerical</p> <p>8 rankings. I've answered that for you.</p> <p>9 I don't do that.</p> <p>10 What I instead do is I'm</p> <p>11 looking at everything that's relevant,</p> <p>12 everything that's available. I do</p> <p>13 categorize it, so I am selecting -- I</p> <p>14 am identifying or analyzing the</p> <p>15 information for what it describes.</p> <p>16 And then if you go further on down, I</p> <p>17 try to tell you what I think is</p> <p>18 important about that information.</p> <p>19 The overall conclusions I'm</p> <p>20 drawing in the report, though, when I</p> <p>21 cite to specific studies in the risk</p> <p>22 assessment, the majority of those</p> <p>23 studies I believe that I'm citing for</p> <p>24 you, outside of notice, have to do</p> <p>25 with -- that's more of a warnings</p>

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<p style="text-align: right;">Page 142</p> <p>1 issue -- have to do with the issue of 2 cosmetic talc. Because the human 3 studies are describing cosmetic talc. 4 The NTP studies is a pure talc. Many 5 of the in vitro studies and other 6 animal studies are looking at, 7 quote/unquote, a talc that is not an 8 industrial grade or from a mine that 9 would have -- be looked at in that 10 way. So -- 11 QUESTIONS BY MS. BRANSCOME: 12 Q. You understand that there are 13 different types of cosmetic talc, correct? 14 A. Yes, I am aware. 15 Q. And cosmetic talc can be mined 16 from a number of different mines globally, 17 correct? 18 A. That's correct. 19 Q. And some of the studies that 20 you cite in your report are testing cosmetic 21 talc from other consumer products, for 22 example, Cashmere Bouquet, correct? 23 A. Some. The majority of them are 24 not, but I would agree that some do, yes. 25 Q. Okay. Have you done an</p>	<p style="text-align: right;">Page 144</p> <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. I was simply asking: Did you 3 do an analysis that would allow you to 4 compare the ingredients in another product, 5 like consumer Cashmere Bouquet, before you 6 rendered an opinion with respect to Johnson's 7 baby powder based on tests of Cashmere 8 Bouquet? Did you do that analysis? 9 MR. MEADOWS: Objection. 10 THE WITNESS: I do not have 11 access to internal company documents 12 for the manufacturers of Cashmere 13 Bouquet, so I certainly couldn't do 14 the analysis in the same way that I 15 can do it here, where I can identify 16 what Johnson & Johnson and Imerys 17 describe as sources of the talc that 18 was used for the Johnson & Johnson 19 baby powder, without -- 20 QUESTIONS BY MS. BRANSCOME: 21 Q. So you have no way of knowing 22 one way or the other whether that talc is 23 similar, correct? 24 MR. MEADOWS: Objection. 25 MS. PARFITT: Objection.</p>
<p style="text-align: right;">Page 143</p> <p>1 analysis of how the talc that is used in 2 Cashmere Bouquet, for example, relates to the 3 talc that is used in Johnson's baby powder? 4 Is that an analysis that you 5 have done before relying on that information 6 in your report? 7 MR. MEADOWS: Objection. 8 MS. PARFITT: Objection. 9 THE WITNESS: My analysis -- I 10 did do an analysis to look at what was 11 described, what products are 12 described, but I certainly -- I 13 certainly did not throw out studies 14 that described Cashmere Bouquet 15 because I would -- I still believe as 16 a toxicologist and a risk assessor 17 that those types of products are 18 important to the overall weight of the 19 evidence about the hazard and the 20 risks posed by talc. 21 You know, I just -- I just -- I 22 guess I disagree with you if you're 23 saying they're irrelevant. I don't 24 believe that they are. 25</p>	<p style="text-align: right;">Page 145</p> <p>1 THE WITNESS: Well, I think I 2 do know it's similar, if you look on 3 the bottle as far as what is described 4 it being, but if you're asking me -- 5 if you're asking did we fingerprint it 6 to only a particular mine, this is the 7 beauty of the data. The data shows 8 that regardless of the type of product 9 you're looking at, there's consistency 10 across the study. 11 So -- but I did not try to 12 segregate out studies that only dealt 13 with Cashmere Bouquet, no, I did not 14 do that. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. Okay. As you sit here today as 17 a toxicologist, is it your position that 18 industrial-grade talc that might contain up 19 to 70 percent tremolite presents the same 20 level of toxic effect as cosmetic talc that 21 may contain no tremolite or tremolite at a 22 very, very low level? 23 MS. PARFITT: Objection. Form. 24 THE WITNESS: I haven't formed 25 that opinion, no.</p>

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<p style="text-align: right;">Page 146</p> <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Okay. And so have you formed 3 an opinion that I could find in your report 4 that discusses in any way the relative 5 toxicity of different types of talc? 6 A. That, you may find. I need to 7 go back and look how I set it out, but I 8 think I -- I talked with you about the 9 difference between fibrous versus platy. I 10 do discuss that. 11 And I talk about the problems 12 when you have a complex mixture that has 13 added to it things like asbestos and heavy 14 metals, because I talk about the additivity 15 issue that can come to play. So that -- in 16 other words, increased risk when you have a 17 complex mixture with additional components 18 that all share the same toxic properties as 19 far as target organs or types of effects or 20 mechanisms that are triggered in the body. 21 That's what I point you to. 22 I -- I don't -- that's the only 23 way I can answer that for you, I think, based 24 on what I know I have in here. 25 Q. Okay. You talk about the term</p>	<p style="text-align: right;">Page 148</p> <p>1 identified characteristics. 2 There's -- within the 3 asbestos -- the asbestos literature 4 there's -- it's one of the forms -- forms of 5 asbestos that's described. For example, in 6 IARC, they describe all of the ones that have 7 carcinogenic properties. It's one of them. 8 Within the literature within 9 Johnson & Johnson's documents, there's 10 tremolite discussed as -- I assume them 11 referring to asbestos tremolite, asbestos in 12 a tremolite characteristic. I have seen 13 tremolite talc also mentioned in the 14 literature. 15 If you want a specific 16 discussion of each of those, again, 17 there's -- I understand there's experts that 18 are going to describe the distinguishing 19 characteristics of each of those. 20 I'm only setting out this is 21 what I have seen, talked about, in the 22 literature. 23 Q. So you are not an expert on the 24 differences between fibrous talc, asbestiform 25 talc, non-asbestiform talc and tremolite as</p>
<p style="text-align: right;">Page 147</p> <p>1 "asbestiform talc." 2 You talk about asbestiform 3 talc. 4 Are you familiar with that? 5 A. I do mention that in my report, 6 yes. 7 Where are you? 8 Q. At paragraph 30. It's on 9 page 19 of your report. 10 A. Yes, I'm here. 11 Q. Okay. And the first sentence 12 in paragraph 30 you state, "In the published 13 medical literature, there is often discussion 14 of talc using terms such as fibrous talc, 15 asbestiform talc, non-asbestiform talc or 16 tremolite." 17 Do you see that? 18 A. Yes, I do. 19 Q. Okay. Is it your opinion that 20 tremolite is a form of talc? 21 A. So tremolite is a -- is a -- is 22 a type of fiber or a -- tremolite is a -- is 23 a substance or a entity that has been 24 identified as a specific morphology, I guess, 25 identified characteristics of a -- it has</p>	<p style="text-align: right;">Page 149</p> <p>1 it relates to toxicity. Is that your opinion 2 today? 3 A. No, that's not what I'm saying. 4 I'm saying that if you want me to -- I'm -- 5 if you want me to describe the 6 characteristics and the morphology of each of 7 those individually, that's something a 8 geologist would do. 9 But certainly as far as the 10 toxicity assessment I did, each of these 11 types of -- each of these words, I guess, or 12 names have been applied in the literature 13 when they talk about toxicity of talc. Some 14 of the literature talks about fibrous talc or 15 just -- other literature just talks about 16 talc. Some of it, for example, the IARC 17 monographs, distinguish between asbestiform 18 talc and non-asbestiform talc in their 19 assessments of the cancer risk. 20 And then tremolite is discussed 21 as a component of talc. And I have seen 22 papers that talk about tremolite -- 23 nontremolite talc or tremolite-containing 24 talc. That's how you most often see it. 25 So it's the idea that it is a</p>

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Page 150	Page 152
<p>1 constituent of certain mines that -- and 2 that's my understanding of it. But if you 3 want -- and they all -- they all certainly do 4 show that the toxicity can be affected, 5 whether it's a fiber or a platy particle. So 6 tremolite being a fiber would certainly 7 affect my overall assessment of risk. The 8 more tremolite that you would have would 9 make -- would make it more likely to be 10 reactive in terms of a foreign body response, 11 depending on the size. 12 Q. What's your basis for saying 13 that? 14 A. That's based on a fibrous form 15 versus a platy particle form. That's the 16 issue of -- I have that paragraph where I 17 talk about what macrophages look for, can 18 engulf or not engulf. So those are all 19 things that are important to a toxicologist 20 to understand exist. 21 But certainly within my 22 assessment I have to include literature from 23 all of those because of the fact that all of 24 those are relevant to the toxicity profile, 25 since I know that the cosmetic baby powders</p>	<p>1 Q. Okay. And so when you're 2 looking at a complex mixture, you would agree 3 as a toxicologist it would be important to 4 understand the constituent elements of that 5 mixture, correct? 6 A. Yes, it is important to 7 understand that this is -- what is in the 8 mixture, and that's -- that's part of what I 9 try to do. 10 Q. Okay. And it would be 11 important before drawing conclusions from one 12 study that might have different constituent 13 components, it's important to understand the 14 relative toxicity of individual constituent 15 elements, correct? 16 A. Depends if you can or not. I 17 mean, there's certain types of studies you 18 can, where in the published literature that's 19 been described. That's why I'm pointing this 20 out. It's the idea that within the 21 literature, when you go through, it's 22 important to understand what you can say 23 about the consistency across the literature 24 where maybe different types of talc are 25 discussed.</p>
Page 151	Page 153
<p>1 and the data I've seen shows detection of 2 something called fibrous talc. 3 I see detection of tremolite 4 within certain samples of baby powder. 5 And then I have just the 6 general category of asbestiform versus 7 non-asbestiform when I consider the way, for 8 example, IARC has reviewed the 9 carcinogenicity. 10 So those are -- those are terms 11 that I'm laying out because I think they are 12 something you need to understand exists in 13 the literature. 14 Q. Okay. But I'm trying to 15 understand, not helping me understand the 16 literature. I'm trying to understand your 17 opinions with respect to toxicity. 18 Is it, for example, your 19 opinion that fibrous talc has the same toxic 20 potential -- let's focus specifically with 21 respect to ovarian cancer -- as tremolite? 22 A. I haven't formed that opinion, 23 but, again, I would -- my opinion has been 24 formed on the fact that we have complex 25 mixture that includes all of these things.</p>	<p>1 And that's what I -- I think I 2 lay out for you. I tell you there's 3 consistency in certain toxic effects that are 4 seen. Regardless of the form that you're 5 looking at, talc has certain properties, and 6 all of these things are -- been shown to be 7 in the complex mixture, so I have -- as a 8 result, all of that literature has relevance 9 to at least the hazard part of my assessment, 10 and certainly have relevance to -- when you 11 want to talk about warning and the final risk 12 assessment, they're definitely relevant, but 13 certainly the -- when I go through this 14 process, I am trying to focus as much as I 15 can on a product that is most similar to the 16 one I'm assessing. 17 So obviously that's why -- 18 that's one of the reasons I do look at the 19 human data, because the human data is 20 involving a consumer product use, which is 21 what I'm talking about here. 22 Q. Is it using specifically 23 Johnson's baby powder? 24 A. Many of them are, yes. 25 Q. Okay.</p>

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Page 154	Page 156
<p>1 A. Based on my understanding of 2 what I see discussed within the literature. 3 Q. Did you identify in your report 4 specifically which report -- which studies 5 have used a consumer product manufactured by 6 Johnson & Johnson? 7 A. I haven't laid them out 8 individually, no, but I am aware of 9 discussions of this general issue within some 10 of the documents I've seen, and essentially 11 Johnson's body powders products were the 12 overwhelming share of the market. 13 Q. But you would agree that 14 studies that did not involve the consumer 15 product manufactured by Johnson & Johnson 16 should be given less weight when analyzing 17 whether or not there are risks associated 18 specifically with Johnson & Johnson's 19 products? 20 MS. PARFITT: Objection. Form. 21 MR. MEADOWS: Objection. 22 THE WITNESS: It depends on the 23 question being asked within the 24 assessment, the risk assessment. It 25 really does, I mean, because each of</p>	<p>1 across the studies that are dealing 2 with not the consumer product but 3 other descriptions, there is a 4 consistency in the types of effects 5 you see. 6 And since I'm not quantifying 7 the risk but identifying it as being 8 increased or not, in other words, is 9 it more likely than not that someone 10 exposed in this way could be at a risk 11 of ovarian cancer, that's what I'm 12 talking about. 13 So again, it's -- if I was 14 trying to identify differences in 15 cancer potency factors for different 16 types, then, yes, if I had an animal 17 study on each of those, I could 18 compare potency for cancer, but that 19 hasn't been done. 20 QUESTIONS BY MS. BRANSCOME: 21 Q. Okay. 22 A. So instead, what I have to do 23 is rely on what is available to me. And 24 based on my judgment, that's how I review the 25 studies.</p>
Page 155	Page 157
<p>1 these studies brings a piece of 2 evidence to the risk assessment. 3 And so the question is -- for 4 each one, you consider it on a 5 case-by-case basis. It is possible, 6 yes, that you would give less weight. 7 It's also possible that you would not, 8 dependent upon what you know about 9 that study and how it relates to other 10 studies that are out there. 11 QUESTIONS BY MS. BRANSCOME: 12 Q. So methodologically, how would 13 I understand from your report marked as 14 Exhibit 4 under what circumstances to give a 15 study that relates to, for example, 16 industrial talc less weight than a study that 17 actually used Johnson's baby powder? 18 MR. MEADOWS: Objection. 19 THE WITNESS: Well, I've tried 20 to tell you that. That's what I said 21 for you. That's why I am doing it. I 22 certainly am trying to focus in on 23 studies that deal with the consumer 24 product. 25 But what I find when I look</p>	<p>1 Q. And so for the opinions that 2 you are offering in the MDL, you agree that 3 you are not quantifying the risk associated 4 with Johnson's baby powder, SHOWER TO SHOWER® 5 or Shimmer with respect to the potential for 6 causing ovarian cancer? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: In terms of a 9 cancer potency factor, that is true, I 10 am not. Instead, what I am doing is I 11 am quantifying whether or not I 12 believe that the risk is increased 13 above a background risk. 14 That has to do with -- that's 15 where I bring in, in my risk 16 assessment, the human data, because 17 the human data is showing 18 statistically significant increases in 19 risk in populations using the consumer 20 product. 21 So I have a quantification 22 where I'm using the word "increased," 23 and I believe to a reasonable degree 24 of medical certainty that indeed the 25 risk is increased. So I'm quantifying</p>

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Page 158	Page 160
<p>1 in that way, but I'm not giving it a 2 number. I'm not saying that the 3 cancer potency factor is such that you 4 increase the risk from one in a 5 million to 10 in a million to 1 in a 6 thousand. That I have not done 7 because I don't have the data, the 8 studies. The company has not done 9 studies on each of these to allow me 10 to do that. 11 QUESTIONS BY MS. BRANSCOME: 12 Q. Okay. The reference that you 13 made to the human data that you believe shows 14 a statistically increased risk in populations 15 using the consumer product, have -- which -- 16 have you identified in your report which of 17 those studies are specifically using a 18 product that was manufactured by Johnson & 19 Johnson? 20 A. I don't lay that out for my 21 report, I do not, but certainly it is 22 something that for some of the studies I 23 believe you can -- you might be able to get 24 some of that information from. But certainly 25 I have not laid that out individually in my</p>	<p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. In reaching your opinion in the 3 MDL that there is an increased risk above 4 background of ovarian cancer from the use of 5 products manufactured by Johnson & Johnson, 6 have you made an attempt to identify 7 specifically which studies, the human studies 8 on which you rely, test or look at people who 9 have used Johnson & Johnson's products? 10 MS. PARFITT: Objection. Form. 11 THE WITNESS: It's my -- my 12 review of the study indicates that I 13 would say for the vast majority of 14 them you cannot do that. 15 But you can take what is 16 reported and look at things such as 17 market share and those kind of things 18 to get an idea of what you believe the 19 exposure would have been. 20 But certainly I have not -- I 21 have not tried to apply some kind of a 22 numerical value to how many people in 23 the study may have used Johnson's baby 24 powder or not, no, that has not been 25 done. I don't think anybody -- any of</p>
Page 159	Page 161
<p>1 report, no. 2 Q. And you would agree that for 3 some of those studies there is no information 4 as to the specific type of consumer talc that 5 the individuals who are being studied used, 6 correct? 7 MS. PARFITT: Objection. Form. 8 THE WITNESS: I would agree 9 that in some of those studies they're 10 not saying, but that is why you look 11 at the evidence overall. 12 And what's important to look at 13 in terms of now -- if you wanted to go 14 to Bradford Hill, that's why you look 15 at things such as consistency. So 16 what do the studies show. We see a 17 certain level of increased risk across 18 studies, regardless of who did the 19 study or what population was being 20 looked at. 21 So that's the best way I can 22 answer that for you. That is -- that 23 is part of the -- of the assessment 24 that you look at. 25</p>	<p>1 the bodies that have looked at this 2 have done that. 3 QUESTIONS BY MS. BRANSCOME: 4 Q. You have not done a market 5 share analysis, correct? 6 A. No, I've seen this in documents 7 only. I have not done my own. There are 8 company documents that talk about their 9 market share. 10 Q. Okay. Have you made an attempt 11 to examine the levels of fibrous talc or 12 asbestiform talc that are in different 13 consumer products, aside from Johnson's baby 14 powder or SHOWER TO SHOWER® or Shimmer? 15 A. So for that are you referring 16 to things such as -- other types of cosmetics 17 like foundations or lipsticks or -- 18 Q. I'll rephrase. 19 Have you made any attempt to 20 examine whether other cosmetic talc body 21 powders have a different percentage of 22 fibrous, or what you refer to as asbestiform 23 talc, from the Johnson & Johnson products? 24 Have you done any analysis to 25 make that comparison one way or the other?</p>

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Page 162	Page 164
<p>1 MS. PARFITT: Objection. Form.</p> <p>2 THE WITNESS: I certainly</p> <p>3 haven't done -- I certainly didn't do</p> <p>4 a directed analysis to try to</p> <p>5 determine that, but there is</p> <p>6 information, I believe, in -- I think</p> <p>7 if you look at some of Dr. Longo's</p> <p>8 work, that may be there.</p> <p>9 And I believe in Dr. Blount's</p> <p>10 published paper there may be a</p> <p>11 discussion of the type of powder</p> <p>12 product used, where she was looking</p> <p>13 for -- at least for asbestiform --</p> <p>14 asbestos within the talc. It may be</p> <p>15 tremolite as well, but -- if you want</p> <p>16 me to look, I can do that. I just</p> <p>17 don't recall whether -- I think she</p> <p>18 did talk about sources of the talc,</p> <p>19 where it came from, so...</p> <p>20 QUESTIONS BY MS. BRANSCOME:</p> <p>21 Q. Okay. But as you sit here</p> <p>22 today, you can't point me to any analysis</p> <p>23 that you did or an analysis that you relied</p> <p>24 on that would relate different brands of</p> <p>25 cosmetic talc body powders with respect to</p>	<p>1 that I state for you that it's my</p> <p>2 opinion that Cashmere Bouquet has this</p> <p>3 specific pattern of constituents as</p> <p>4 compared to Johnson & Johnson's. No,</p> <p>5 I have not done that.</p> <p>6 QUESTIONS BY MS. BRANSCOME:</p> <p>7 Q. Okay. And that would be true</p> <p>8 for any other brand of cosmetic talc, body</p> <p>9 powders, Jean Nate, Lily of the Valley, not</p> <p>10 just Cashmere Bouquet, correct?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 THE WITNESS: That is correct,</p> <p>13 I don't have access to that</p> <p>14 information.</p> <p>15 QUESTIONS BY MS. BRANSCOME:</p> <p>16 Q. Have you done any analysis of</p> <p>17 the constituent components of talc and how</p> <p>18 they have changed even within Johnson's --</p> <p>19 Johnson & Johnson's manufactured products,</p> <p>20 how the constituents of the consumer products</p> <p>21 may or may not have changed over time?</p> <p>22 A. I've done some of that, yes,</p> <p>23 and I laid that out, I think, for you, when I</p> <p>24 talk about the differences in the products</p> <p>25 that are described within the documents, the</p>
Page 163	Page 165
<p>1 their constituent components?</p> <p>2 MS. PARFITT: Objection.</p> <p>3 Completely misstates her testimony.</p> <p>4 She mentioned Dr. Blount. She</p> <p>5 mentioned others.</p> <p>6 THE WITNESS: So I think what I</p> <p>7 started with, I said I haven't done a</p> <p>8 directed analysis to try to determine</p> <p>9 specifically how this product versus</p> <p>10 this product versus this product may</p> <p>11 have looked over time, because I don't</p> <p>12 have access to a full data to do that.</p> <p>13 But what I do have is data that</p> <p>14 has -- I do see published data, for</p> <p>15 example, Blount and maybe some of the</p> <p>16 other published studies, that looked</p> <p>17 at this issue, at least of asbestos</p> <p>18 presence in talc. And I believe</p> <p>19 Dr. Longo also had things that weren't</p> <p>20 just Johnson's. I believe he had</p> <p>21 Cashmere Bouquet, for example, samples</p> <p>22 in some of the things he looked at.</p> <p>23 So I can point you to those</p> <p>24 things that I have reviewed, but I</p> <p>25 haven't -- there's nowhere in here</p>	<p>1 company documents, from the '70s versus the</p> <p>2 '80s versus later on, as far as the changes</p> <p>3 that were made to specifications of the</p> <p>4 product, for example. That's something --</p> <p>5 and I think I've talked about that a bit at</p> <p>6 trial as well.</p> <p>7 Q. Okay. And is it your view that</p> <p>8 the risk potential for Johnson & Johnson's</p> <p>9 manufactured products have changed at all</p> <p>10 over time with respect to ovarian cancer?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 THE WITNESS: I have not -- I</p> <p>13 have not attempted to differentiate a</p> <p>14 risk potential at only one point in</p> <p>15 time.</p> <p>16 What I have done over points of</p> <p>17 time is looked at the issue of</p> <p>18 warnings and what should be warned</p> <p>19 about.</p> <p>20 But my analysis related to the</p> <p>21 hazard or the risk assessment of the</p> <p>22 products is considering all of the</p> <p>23 available information, which would be</p> <p>24 all of that information over time.</p> <p>25</p>

42 (Pages 162 to 165)

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<p style="text-align: right;">Page 166</p> <p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Okay. You talk about, in 3 paragraph 35 primarily -- we'll talk about 4 the fragrance components in more detail, but 5 you talk about the idea of chemicals being a 6 potential irritant. 7 Are you familiar with that? 8 A. Yes, that's correct. 9 Q. Is it your position that any 10 product that contains chemicals that could be 11 an irritant should be labeled with a health 12 warning? 13 MS. PARFITT: Objection. 14 MR. MEADOWS: Okay. 15 THE WITNESS: I don't think 16 that's -- no, I don't think I've 17 formed that specific opinion. 18 But the opinion that I think 19 I'm expressing here is that when you 20 have a -- the information that I have, 21 which unfortunately the company hasn't 22 given us percentages or actual levels, 23 instead, what I do as a toxicologist, 24 I look at what is there. And when I 25 see over a hundred chemicals there,</p>	<p style="text-align: right;">Page 168</p> <p>1 you with specific percentages, and so I'm 2 asking you, is that something that as a 3 toxicologist would be important information 4 to you? 5 A. Depends. Certainly with the 6 fragrance -- and I'm talking about the 7 conversation about this paragraph is focusing 8 on the fragrance components. 9 So, yes, I mention that it 10 would be nice to know, it would be good to 11 know, if we could, exactly what was in there, 12 because I could quantify the hazard or 13 quantify the risk, actually. So instead, I 14 have -- I identify it as a hazard, but I 15 can't quantify it without those levels. 16 But does that change -- make a 17 difference in the overall conclusions I draw? 18 No, it doesn't affect the overall conclusions 19 that I have drawn, but it adds that other 20 piece of the puzzle that deals with the fact 21 that we have a complex mixture that have a 22 combination of ingredients that target 23 irritation. 24 And irritation and the 25 potential to produce an inflammatory</p>
<p style="text-align: right;">Page 167</p> <p>1 that 70 percent of them have been 2 linked as an irritant hazard, there is 3 the issue of toxicological additivity 4 to consider. 5 So certainly as a risk 6 assessor, when I have that many 7 potential sources of irritation as far 8 as chemicals going into a complex 9 mixture, certainly I think I have 10 formed the opinion that I think that 11 is something that needs to be 12 considered when you're talking about 13 providing information to consumers, 14 yes. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. As a toxicologist, would it be 17 important to you to understand the exact 18 percentages of all of the constituent 19 components of, say, Johnson's baby powder, 20 for example? 21 A. Are you talking about just the 22 fragrance or are you talking about everything 23 that's in it? 24 Q. Dr. Plunkett, you referenced 25 the fact that the company has not provided</p>	<p style="text-align: right;">Page 169</p> <p>1 response, in my -- if you've read my report, 2 you understand that I think that's a key 3 factor in increasing the risk for ovarian 4 cancer. 5 Q. Understanding the percentages 6 of the constituent components, is that 7 limited only to fragrance, or would it also 8 be important to understand the percentages 9 for the heavy metals that you contend are in 10 Johnson's baby powder? 11 A. So if I was trying to define 12 the hazard of each component, I would 13 certainly want one to know that. As a 14 result, what I'm doing instead is looking at 15 the complex mixture. In other words, this is 16 a mixture of all these things. 17 I break out those individual 18 components, or constituents, to tell you 19 about the hazard that is brought to play or 20 the toxicity profiles that exists. And 21 what's important about that in my overall 22 evaluation of the end product, which is what 23 my risk assessment is based on, the end 24 product, shows that I have multiple 25 components with similar types of effects.</p>

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Page 170	Page 172
<p>1 And as a toxicologist, when you do that, that</p> <p>2 affects the conclusion that you can draw</p> <p>3 about a body of literature.</p> <p>4 Q. Okay. You do understand that</p> <p>5 there is testing data available about the</p> <p>6 percentages of the constituent components</p> <p>7 with respect to heavy metals, et cetera, that</p> <p>8 have been in Johnson's baby powder over time,</p> <p>9 correct?</p> <p>10 A. There is some information.</p> <p>11 Unfortunately, the information is not</p> <p>12 complete as to every lot or every sample, as</p> <p>13 far as what I have seen. And also, there's</p> <p>14 some -- some of the sampling is reported as</p> <p>15 more of a limit versus an actual</p> <p>16 quantification. So it depends upon which --</p> <p>17 which result, study result or document,</p> <p>18 you're looking at.</p> <p>19 There is some there, yes, and</p> <p>20 that's one of the reasons why I identified</p> <p>21 these as part of my risk assessment, because</p> <p>22 I look for a pattern of these metals that are</p> <p>23 known to carry a hazard and whether or not</p> <p>24 these are ones I'm seeing detected time and</p> <p>25 time again.</p>	<p>1 using a word such as an increase -- an</p> <p>2 increased risk.</p> <p>3 Is that a specific number? Am</p> <p>4 I telling you that it's increased by two</p> <p>5 times or four times or six times? No. The</p> <p>6 data available did not allow us to do that,</p> <p>7 with the exception of the epidemiological</p> <p>8 data. And the epidemiological data can show</p> <p>9 you that in that piece of evidence there</p> <p>10 appears to be a 30 percent increased risk</p> <p>11 above background.</p> <p>12 Q. Did you make an attempt to</p> <p>13 quantify the risk with the data that you had</p> <p>14 available to you with respect to the final</p> <p>15 consumer product?</p> <p>16 A. I could not, based on the data</p> <p>17 I had, because I didn't have a</p> <p>18 well-controlled animal study to be able to</p> <p>19 pull that out that way.</p> <p>20 Instead, what I -- in this type</p> <p>21 of weight of the evidence, you look at what</p> <p>22 you might be able to quantify based on the</p> <p>23 human data. And certainly the human data</p> <p>24 showing the statistically significant</p> <p>25 consistent findings across studies for that</p>
Page 171	Page 173
<p>1 Q. But you made no attempt to</p> <p>2 quantify the risk with respect to any of</p> <p>3 those components or use that data in any way,</p> <p>4 correct?</p> <p>5 MS. PARFITT: Objection. Form.</p> <p>6 THE WITNESS: No, I used</p> <p>7 that -- that data as part of -- my</p> <p>8 risk assessment as part of my hazard</p> <p>9 assessment, absolutely. It's part of</p> <p>10 the hazard assessment.</p> <p>11 But as far as quantifying them</p> <p>12 individually, no. I am quantifying</p> <p>13 the risk and looking at the risk of</p> <p>14 the entire product, not of just one</p> <p>15 individual component of the product.</p> <p>16 QUESTIONS BY MS. BRANSCOME:</p> <p>17 Q. Well, we already discussed</p> <p>18 you're not quantifying the risk with respect</p> <p>19 to the entire product, correct?</p> <p>20 A. Well, I'm quantifying it in</p> <p>21 terms of an increase above background, which</p> <p>22 I'm not giving you a -- I told you I wasn't</p> <p>23 giving you a cancer potency factor. That is</p> <p>24 true. That I am not doing.</p> <p>25 But I am quantifying it by</p>	<p>1 30 percent increased risk, that is part of my</p> <p>2 overall weight of the evidence for me making</p> <p>3 the statement the risk is increased.</p> <p>4 But you'll notice I don't say</p> <p>5 increased risk of 30 percent, because I don't</p> <p>6 believe that I can state that with certainty</p> <p>7 in the way I do a risk assessment. But</p> <p>8 certainly as any one individual -- any one</p> <p>9 individual piece of evidence or any one body,</p> <p>10 like the epi data, others have made -- other</p> <p>11 bodies who have looked at the -- talked about</p> <p>12 the consistency of the increased risk signal</p> <p>13 in the epi studies as being in the range of</p> <p>14 30 percent.</p> <p>15 Q. Okay. But you would agree that</p> <p>16 based on the methodology that you applied in</p> <p>17 this case, you could not say to a reasonable</p> <p>18 degree of scientific certainty that there is</p> <p>19 an increased risk of, for example, 30 percent</p> <p>20 with respect to use of Johnson's baby powder</p> <p>21 and ovarian cancer, correct?</p> <p>22 MR. MEADOWS: Objection.</p> <p>23 THE WITNESS: I have not done</p> <p>24 that. And I'm not saying that</p> <p>25 somebody else couldn't do that. I</p>

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<p style="text-align: right;">Page 174</p> <p>1 have not -- I have not chosen to do 2 that based on my evaluation of the 3 data. 4 QUESTIONS BY MS. BRANSCOME: 5 Q. And the same would be true if I 6 asked that question and substituted any 7 particular number, a 10 percent increased 8 risk, a 20 percent increased risk, correct? 9 MR. MEADOWS: Objection. 10 THE WITNESS: I haven't given a 11 specific number in my final opinions, 12 that is true. 13 QUESTIONS BY MS. BRANSCOME: 14 Q. Okay. 15 A. I've tried to explain to you 16 what evidence I do think is there, however. 17 Q. Now, we've talked about 18 different types of talc that might have 19 different constituent components, but you 20 also look at exposure to talc in an 21 occupational setting. 22 Do you recall that? 23 A. Some of the studies that I've 24 relied upon, yes, some of them were 25 occupational.</p>	<p style="text-align: right;">Page 176</p> <p>1 Q. Is it your opinion as you sit 2 here today that someone could develop ovarian 3 cancer through -- exclusively through the 4 inhalation of Johnson's baby powder? 5 MS. PARFITT: Objection. 6 THE WITNESS: I haven't formed 7 that opinion at this point in time. 8 QUESTIONS BY MS. BRANSCOME: 9 Q. Have you done any analysis or 10 can you point me to any analysis in your 11 report that makes a comparison of the 12 exposure levels that might be seen in an 13 occupational setting to what would be seen by 14 a consumer? 15 A. Are you asking me for a piece 16 of evidence that does that comparison, or is 17 there evidence that allows you to do that 18 comparison? 19 Q. Have you cited or discussed any 20 of the evidence or done an analysis in any 21 way that would compare exposure levels in an 22 occupational setting to what you would 23 anticipate a consumer using Johnson's baby 24 powder might be exposed to? 25 A. I don't think I did it as a</p>
<p style="text-align: right;">Page 175</p> <p>1 Q. Okay. And you understand that 2 in an occupational setting, you would agree 3 that the exposure, particularly via 4 inhalation, would be much higher than it 5 would be through the use of a consumer 6 product, correct? 7 A. It depends on the occupation, 8 but, yes. For example, I would agree a miner 9 would be expected to have that, but there are 10 certain, quote/unquote, occupational studies 11 where the exposure levels that -- for 12 example, there are -- I believe there's at 13 least one study that looked at application of 14 talc powders in -- maybe in a material, 15 coating materials in a factory. Those kinds 16 of studies would be different than a mining 17 study. 18 But, certainly, yes, I 19 understand that occupational studies, the 20 inhalation exposure is the pathway that would 21 be predominant versus in the consumer body 22 powder use, I'm talking about the predominant 23 exposure pathway in my opinion is going to be 24 through perineal use, even though inhalation 25 exposure can occur.</p>	<p style="text-align: right;">Page 177</p> <p>1 separate analysis, but as part of my analysis 2 I considered evidence that showed -- provided 3 me with such data. So, for example, if you 4 want, I can point you to a -- I have an 5 inhalation paragraph, I think. 6 Let me look for it real quick. 7 See if I can find it quickly for you. I 8 don't want to waste your time. 9 Q. Sure. 10 A. So there's -- I don't see it 11 cited here, but there's at least one document 12 I reviewed where the company themselves made 13 a comparison, and I have seen that, of 14 inhalation exposure to talc suspended in air 15 with diapering. Dr. Longo has done a 16 measurement of exposure in air with perineal 17 application of talc. So I'm aware of those 18 studies. 19 And then I certainly am aware 20 of the fact that those numbers are different, 21 or smaller, than many of the numbers I see 22 reported in some of the occupational studies. 23 But I can't say that's true for all. 24 I would certainly, though, say 25 that if you're just talking inhalation, I</p>

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<p style="text-align: right;">Page 178</p> <p>1 certainly would expect a miner or a miller to</p> <p>2 have a greater potential for inhalation</p> <p>3 exposure than routine use of the consumer</p> <p>4 product, with the exception of the studies --</p> <p>5 the reports of large amounts of exposure in</p> <p>6 children where the inhalation -- where they</p> <p>7 were inhaling large amounts of powder.</p> <p>8 And so that's a different</p> <p>9 story. That's sort of an acute overdose</p> <p>10 exposure, I guess, versus the typical daily</p> <p>11 exposure through occupational or consumer</p> <p>12 use.</p> <p>13 Q. And that raises an interesting</p> <p>14 question. You discuss health hazards</p> <p>15 associated with talc being known, and in some</p> <p>16 cases deaths had been reported.</p> <p>17 You're aware that those relate</p> <p>18 to asphyxiation deaths, correct?</p> <p>19 A. Or long-term injury to lungs.</p> <p>20 Maybe not an immediate asphyxiation, but lung</p> <p>21 damage produced by large amounts -- some of</p> <p>22 the children would go to the hospital and be</p> <p>23 sick for a while and then die. So they</p> <p>24 didn't asphyxiate immediately, right? But</p> <p>25 some of them did. You're exactly right.</p>	<p style="text-align: right;">Page 180</p> <p>1 QUESTIONS BY MS. BRANSCOME:</p> <p>2 Q. Okay. Now, you would agree</p> <p>3 that -- so let's set aside inhalation.</p> <p>4 You agree that for talc -- for</p> <p>5 Johnson's baby powder or another one of</p> <p>6 Johnson & Johnson's consumer talc products to</p> <p>7 reach an individual's ovaries, it must pass</p> <p>8 from the perineum, through the vagina and the</p> <p>9 cervical canal, move across the uterus -- and</p> <p>10 again, it's the ciliary motion of the</p> <p>11 fallopian tubes -- cross the peritoneal space</p> <p>12 between the fimbriae and ovaries, escape</p> <p>13 phagocytosis in the peritoneal space, and</p> <p>14 then attach to the surface of the ovaries,</p> <p>15 correct?</p> <p>16 MS. PARFITT: Objection. Form.</p> <p>17 MR. MEADOWS: Okay.</p> <p>18 THE WITNESS: If the issue is</p> <p>19 attaching to the surface, yes.</p> <p>20 There's also some information</p> <p>21 indicates the site of attack may be</p> <p>22 actually at the fallopian tube exit to</p> <p>23 the peritoneum. But, yes, that's</p> <p>24 correct, there's been some discussion</p> <p>25 in the literature on ovarian cancer</p>
<p style="text-align: right;">Page 179</p> <p>1 Both of those things occur, and</p> <p>2 I address that also in my warning section</p> <p>3 about the fact that that warning didn't --</p> <p>4 was not put on the product for a long period</p> <p>5 of time even though those types of reports</p> <p>6 were coming in early.</p> <p>7 Q. You would agree that that is a</p> <p>8 completely different biologic mechanism than</p> <p>9 what you are proposing the biological</p> <p>10 mechanism is for ovarian cancer to develop</p> <p>11 with respect to talc use, correct?</p> <p>12 MR. MEADOWS: Objection.</p> <p>13 THE WITNESS: I would agree</p> <p>14 that it's an acute response versus</p> <p>15 chronic, yes, that I agree with.</p> <p>16 It's not entirely different in</p> <p>17 some cases because some of the tissue</p> <p>18 reactions you saw were indicative of</p> <p>19 irritation when some of the lung</p> <p>20 samples were looked at. But</p> <p>21 certainly, yes, that's acute exposure</p> <p>22 versus chronic exposure, and I'm</p> <p>23 focusing on ovarian cancer on chronic</p> <p>24 exposure scenarios.</p> <p>25</p>	<p style="text-align: right;">Page 181</p> <p>1 about whether the tumors are arising</p> <p>2 in the tubes versus the ovaries.</p> <p>3 But I would agree, I think</p> <p>4 both -- I think both of those</p> <p>5 things -- those things -- there is a</p> <p>6 passage that has to happen, regardless</p> <p>7 of whether the end point is at the</p> <p>8 fallopian tube or at the ovary.</p> <p>9 QUESTIONS BY MS. BRANSCOME:</p> <p>10 Q. Okay. Is it your view that the</p> <p>11 consensus has been reached that ovarian</p> <p>12 cancer can be caused by talc landing in the</p> <p>13 fallopian tubes?</p> <p>14 A. I haven't formed that opinion,</p> <p>15 though I do believe this will be discussed by</p> <p>16 some of the other experts.</p> <p>17 Q. Okay. Have you personally</p> <p>18 conducted any tests or experiments to confirm</p> <p>19 the theory that talc migrates from</p> <p>20 application at the perineum to the ovaries?</p> <p>21 A. If by that you mean something</p> <p>22 where I performed a laboratory test myself,</p> <p>23 no, I have not done that.</p> <p>24 Q. As a toxicologist, are you</p> <p>25 capable of doing that?</p>

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Page 182	Page 184
<p>1 A. Yes, I believe if asked I 2 could -- I could attempt to design something 3 to look at that issue. 4 Q. Okay. 5 A. But I would argue that I think 6 it doesn't make a lot of sense to revisit 7 based upon what we already know from the 8 scientific literature and the review papers 9 from the gynecological community. I believe 10 it's -- it's understood that it can migrate. 11 Q. In your opinion, has an animal 12 model been successfully developed that would 13 allow the testing of talc migration in humans 14 from the perineum to the ovaries? 15 A. I think I tell that you in my 16 report. I believe that the human data is the 17 relevant data to look at this issue. 18 So it would be very difficult 19 to design a study to do this based on the 20 typical laboratory species that are used in 21 toxicology testing. Even -- even the monkeys 22 have issues, and the biggest issues with 23 monkeys is the ethicality of using a monkey 24 to settle -- to address a question that I 25 believe is settled within the gynecological</p>	<p>1 And then on top of that, you 2 have the review articles that talk about 3 migration of particles in the female 4 reproductive tract and are describing it as 5 an event that is known to occur. So it's 6 those things weighed together. 7 But certainly routine could be 8 supported by the observations where the 9 majority of the patients in the studies were 10 showing movement of inert particles. 11 Q. Is it your opinion that every 12 perineal application of cosmetic talc powder 13 results in talc being deposited on the 14 ovaries? 15 A. I have not formed that opinion, 16 no. 17 Q. Have you formed an opinion as 18 to with what frequency -- so let's say 19 someone uses a cosmetic talc on a perineal 20 application ten times. Out of those ten 21 times, have you formed an opinion as to how 22 many of those instances would talc deposit on 23 the ovaries? 24 MS. PARFITT: Objection. 25 THE WITNESS: I haven't formed</p>
Page 183	Page 185
<p>1 and scientific community. 2 Q. Now, you state in your report 3 that talc that's applied through perineal 4 use -- I believe the term you use -- 5 routinely migrates to the ovaries. 6 Is that your opinion? 7 A. Are you reading from my report? 8 MR. MEADOWS: To the extent 9 that question is still lingering, I 10 object to it. 11 QUESTIONS BY MS. BRANSCOME: 12 Q. On paragraph 43 on page 29. 13 A. So I think as I've stated it, 14 the studies that I have reviewed demonstrate 15 that inert particles routinely move from the 16 lower female reproductive tract up into 17 fallopian tubes and towards the ovaries. 18 Q. What do you mean by routinely? 19 A. It's the percentages of 20 movement that are reported in the patients. 21 In other words, if you look at some of the 22 individual studies -- if you want we can pull 23 them out, but, you know, eight of ten 24 patients, nine of ten patients, all the 25 patients showed movement of the particles.</p>	<p>1 an opinion in that particular way, no. 2 I think what I've -- I've tried to 3 describe to you in my report is that I 4 believe it is known that inert 5 particles have the ability to migrate. 6 And based on that, I form the opinion 7 that it's my opinion to a reasonable 8 degree of scientific certainty, which 9 would be a more likely than not 10 standard, that particles of talc would 11 be migrating when women are using them 12 perineally. But I haven't told you 13 that it has to be a specific number, 14 no. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. Have you done any analysis to 17 establish over a lifetime use of cosmetic 18 talc where the app -- the perineal 19 application, with what frequency during a 20 lifetime the talc may have been deposited on 21 that individual's ovaries? 22 A. So I certainly looked for 23 information to allow me to assess that, but 24 unfortunately those kinds of studies would be 25 unethical to do. Because that would be a</p>

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Page 186	Page 188
<p>1 matter of sampling women during -- using them 2 and then taking biopsies, and that's 3 something that would be difficult to do. I 4 would say impossible to get approval to do 5 under human testing guidelines. 6 Q. Okay. So it's your opinion 7 that it is possible for talc that is applied 8 through a perineal application to reach the 9 ovaries, but you cannot say with what 10 frequency that occurs? 11 MS. PARFITT: Objection. Form. 12 Misstates her testimony. 13 THE WITNESS: That's not -- 14 what I'm telling you is, I think it -- 15 that to a reasonable degree of 16 scientific certainty that it migrates, 17 and that would be the standard of more 18 likely than not. I think it's more 19 likely than not that the talc is 20 reaching the ovaries when people are 21 using it perineally. 22 I did form the opinion -- and 23 I've talked about this at trial and 24 yesterday. I have formed the opinion 25 that this is a issue of chronic or --</p>	<p>1 MS. BRANSCOME: Okay. Can we 2 just go off the record for a second? 3 VIDEOGRAPHER: We are going off 4 the record at 12:23 p.m. 5 (Off the record at 12:23 p.m.) 6 VIDEOGRAPHER: We are back on 7 the record at 12:24 p.m. 8 QUESTIONS BY MS. BRANSCOME: 9 Q. As you sit here today, how 10 would you characterize the biological 11 mechanism by which you claim Johnson's baby 12 powder, their other cosmetic talc products, 13 present a risk of ovarian cancer? 14 A. So I outline this for you in 15 the MDL report. I think I have a section 16 on -- let's see if I can -- you want me to 17 tell you where or... 18 So paragraph 65, I think I set 19 out part of this argument or part of this. 20 And then also in paragraph -- I believe in 21 67. 22 Q. All right. Well, let me take a 23 step back. 24 Is it your opinion that the 25 biological mechanism by which talc, cosmetic</p>
Page 187	Page 189
<p>1 or use of the products. In other 2 words, people aren't just using it 3 once, but people are using it -- you 4 can use the word "routinely," as a 5 habit, in their daily life perineally. 6 And that would be consistent with the 7 studies that have been done that have 8 looked at the issue of dose response. 9 And I discuss that in my 10 report, too. 11 QUESTIONS BY MS. BRANSCOME: 12 Q. Okay. But you have not made an 13 attempt to quantify, nor have you seen it in 14 the literature, the overall dose of talc that 15 someone might be exposed to in terms of 16 contact with the ovaries throughout their 17 lifetime, chronic use of cosmetic talc? 18 MS. PARFITT: Objection. Form. 19 THE WITNESS: Those -- that's 20 the kinds of studies that have not 21 been done and I believe could not be 22 done based upon ethics of human 23 testing. But certainly I -- that -- 24 that data is not available that I'm 25 aware of.</p>	<p>1 talc, can in your view cause ovarian cancer, 2 is that something that has been definitively 3 established? 4 A. What do you mean by 5 definitively? I mean, I think -- I believe 6 more likely than not that -- so I believe I 7 have reached a conclusion that I think what 8 the most likely biologically plausible 9 mechanism, but maybe you're ask -- meaning 10 something else. 11 Q. Okay. Well, let's start with 12 specifically you discuss a number of 13 different potential mechanisms in your 14 report. So if you believe you have reached 15 an opinion more likely than not about the 16 specific biological mechanism by which 17 cosmetic talc and specifically Johnson & 18 Johnson's products can cause ovarian cancer, 19 can you describe that for me? 20 A. So it's a chronic inflammatory 21 process, and so -- but like all compounds, 22 constituents, even drugs that we look at, we 23 don't know each individual step within the 24 molecular mechanism. 25 Instead, what we know is that</p>

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Page 190	Page 192
<p>1 there are certain components to the process 2 of cancer that are consistent with the 3 effects produced by talc, and we know that 4 talc can produce a chronic inflammatory 5 process. 6 And so that's why I was 7 pointing you to the paragraph 65 and I think 8 67. 9 Q. Is it your opinion that 10 consensus has been reached in the scientific 11 community that cosmetic talc can cause 12 ovarian cancer through a chronic inflammatory 13 response? 14 MS. PARFITT: Objection. 15 THE WITNESS: I don't know that 16 that's exactly the opinion I've 17 formed. 18 Would you like me to -- I could 19 restate what I believe, but I don't 20 think that's exactly how I would state 21 it, no. 22 QUESTIONS BY MS. BRANSCOME: 23 Q. Okay. So then yes or no: Has 24 consensus been reached in the scientific 25 community that cosmetic talc can cause</p>	<p>1 discuss those issues. 2 I think it's consistent with -- 3 I don't know if the ACOG statement goes that 4 far on mechanism, but it does talk about 5 ovarian cancer. That's a recent statement. 6 And I believe it's consistent 7 with some of the -- I believe my opinions are 8 consistent with some of the opinions reached 9 by others in science, but that's the only way 10 I can answer that for you. 11 Q. Okay. Because you have not, 12 one way or the other, done an evaluation of 13 whether or not chronic inflammatory process 14 is a biological mechanism on which the 15 scientific community has reached general 16 consensus with respect to the causation of 17 ovarian cancer; is that correct? 18 MR. MEADOWS: Objection. 19 THE WITNESS: I can't tell you 20 that -- I can't tell you that every 21 body that's looked at it, but I have 22 tried to point you to evidence that I 23 believe is consistent with that. 24 For example, the IARC would be 25 a good example of consensus on</p>
Page 191	Page 193
<p>1 ovarian cancer through a chronic inflammatory 2 process? 3 A. I don't believe I formed the 4 opinion either way, that it's yes or no, 5 because I haven't tried to -- I haven't tried 6 to form the opinion about what the -- in 7 other words, I haven't -- I can't say for 8 every scientist out there. 9 I certainly can tell you what I 10 believe based on what the consensus of 11 science says about mechanisms underlying 12 cancer and the consistency of those 13 mechanisms with talc, and then I have an 14 opinion about what I believe that information 15 says. 16 I do believe my opinions, 17 however, are consistent with some consensus 18 statements, such as the issue on the 19 mechanism is consistent with consensus 20 opinion reached by IARC, where they discuss 21 the inflammatory process as an underlying 22 biologically plausible mechanism that can 23 lead to ovarian cancer. 24 I think it's consistent with 25 the Canadian risk assessment where they</p>	<p>1 biologic mechanism because they have a 2 whole part of their assessment of 3 non-asbestiform talc and perineal 4 cancer -- of perineal use and ovarian 5 cancer that discusses mechanism. And 6 that is consistent with what I have 7 said. So there is a consensus 8 opinion. 9 But I guess what I'm saying to 10 you is I can't tell you that all -- 11 all people who have put statements 12 have come to that exact opinion. But 13 there aren't that many places out 14 there that are addressing that issue 15 as far as the consensus on a 16 mechanism. There's more statements 17 about the relationship between ovarian 18 cancer and talc use than there are 19 drilling down to what the mechanism 20 must be. 21 QUESTIONS BY MS. BRANSCOME: 22 Q. Okay. 23 A. So that's the issue. It's a 24 little -- it's a little hard to answer that 25 yes or no because of that.</p>

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<p style="text-align: right;">Page 194</p> <p>1 Q. Okay. When we talk about the 2 idea of biologic -- a biologically plausible 3 mechanism, what is your understanding of the 4 term "plausible" in that expression? 5 A. When I use the word 6 "biologically plausible mechanism" or 7 "biologic plausibility," I'm using it 8 consistent with what Bradford Hill uses, 9 that's it's the idea that the evidence that 10 available makes -- the evidence that 11 available supports a pathway where you can go 12 to exposure to response. 13 So in other words, there's a -- 14 the biological information is consistent with 15 how we know cancer can develop. That's the 16 response we're looking at. And the exposure 17 we're looking at is known to produce those 18 kind of biologic events. 19 So as a result, based upon 20 knowing that there's a consistency between 21 the data that we have on the -- on the 22 exposure and the data that we have on the way 23 cancer can occur, those things -- those 24 things align. So that makes it biologically 25 plausible that that could occur.</p>	<p style="text-align: right;">Page 196</p> <p>1 are known to be able to produce, 2 specifically, ovarian cancer. 3 QUESTIONS BY MS. BRANSCOME: 4 Q. Is it your opinion that IARC, 5 for example, has concluded that the 6 biological mechanism by which talc may cause 7 ovarian cancer is chronic inflammation? 8 MS. PARFITT: Objection. 9 THE WITNESS: I don't know that 10 they have used -- they've described it 11 quite that way, but they do describe 12 what they believe is the biologically 13 plausible mechanism. Because they do 14 organize and use within the 15 definitions of how they describe some 16 things that are consistent with what 17 Bradford Hill uses. 18 QUESTIONS BY MS. BRANSCOME: 19 Q. Okay. And obviously you're 20 familiar with the IARC evaluation of talc 21 with respect to the possibility of causing 22 ovarian cancer, correct? 23 A. Yeah. If you mean the recent 24 one, yes, the most recent assessment. 25 Q. Yes.</p>
<p style="text-align: right;">Page 195</p> <p>1 Q. But you would agree that 2 biological plausibility suggests that it is a 3 plausible explanation, but it may not have 4 been established as the definitive pathway by 5 which a disease is caused, correct? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: Well, I would 8 agree that in the discussion of 9 biologic plausibility in the Bradford 10 Hill paper that is true. But if you 11 look at people's discussion of the use 12 of -- I want to say "biological 13 mechanism" rather than the word 14 "biologic plausibility," because 15 really as a toxicologist I'm trying to 16 understand whether there's a biologic 17 mechanism that makes sense. Those are 18 words I like to use. Does it make 19 sense that this exposure could lead to 20 this response. 21 And that involved looking at 22 the mechanistic data or the data on 23 the way toxic responses are produced 24 by talc, and whether or not they align 25 with the types of toxic insults that</p>	<p style="text-align: right;">Page 197</p> <p>1 And that IARC has in fact 2 classified cosmetic talc not containing 3 asbestos as possibly carcinogenic to humans, 4 correct? 5 A. It's a possible human 6 carcinogen 2B, that's correct. 7 Q. Okay. And if a product is 8 listed in the 2B category, does that 9 necessarily mean the product, in your view, 10 is carcinogenic? 11 A. Not always, because that comes 12 down to an assessment of -- then you're 13 putting together a -- a risk assessment that 14 looks at -- looks at -- across the 15 information that you have available. And 16 that may be that -- that the -- the possible 17 is all you can say, or it may be that you 18 believe that the information -- there's 19 enough information there to take it further. 20 Has a possibility -- that's 21 what I said, they do a hazard assessment. 22 They rank things on hazard based on -- on 23 unlikely -- not enough evidence, less -- the 24 possibility, the probability or it's known. 25 Q. In your opinion, is your</p>

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Page 198	Page 200
<p>1 characterization of the risk of Johnson's 2 baby powder or talcum powder products with 3 respect to ovarian cancer, are you in the MDL 4 characterizing that risk as a higher level of 5 risk than what IARC characterized it, or do 6 you agree with the 2B characterization of 7 possibly carcinogenic? 8 MS. PARFITT: Objection. Form. 9 THE WITNESS: So I'm not IARC, 10 so I don't try to second-guess there. 11 They have reached a conclusion, and I 12 use that as part of my weight of the 13 evidence. So I haven't formed the 14 opinion they're right or wrong. 15 But I have done a different 16 assessment. My assessment, first off, 17 includes more information than IARC 18 had, so as a result, I have formed the 19 conclusion that I believe that it's 20 more likely than not that exposure 21 to -- perineal exposure to talc body 22 powders increases the risk of ovarian 23 cancer in women who use that product. 24 And I will put the caveat this 25 has to be chronic use or repeated use,</p>	<p>1 opinion. 2 Q. Is there a threshold of the use 3 of Johnson & Johnson's talcum powder products 4 below which there is no increased risk, in 5 your opinion, of ovarian cancer? 6 A. We have not identified that 7 threshold. That's what's missing within 8 the -- the literature that exists today. So 9 I can't tell you whether or not with only a 10 thousand applications over a lifetime that 11 is -- is not enough for every individual or 12 not, but certainly I do believe that the -- 13 that the exposure has to be habit, routine, 14 chronic, something that is done maybe not on 15 a daily basis but on a routine basis in a 16 woman's life. 17 So that is consistent, I think, 18 with the literature. 19 MS. BRANSCOME: Okay. We can 20 go off the record. 21 VIDEOGRAPHER: We are going off 22 the record at 12:36 p.m. 23 (Off the record at 12:36 p.m.) 24 VIDEOGRAPHER: We are back on 25 the record at 1:35 p.m.</p>
Page 199	Page 201
<p>1 because I've gone -- I've said that 2 many times. 3 So that -- that is my opinion. 4 So that's a different statement and a 5 different assessment than what IARC 6 does. 7 But -- so I don't disagree with 8 their possible -- I weigh that, but I 9 believe the evidence for the risk 10 assessment shows me that it's more 11 likely than not that this -- this 12 exposure will increase the risk above 13 a background risk for women who are 14 using this product. 15 QUESTIONS BY MS. BRANSCOME: 16 Q. And how do you define chronic 17 or repeated use? 18 A. Well, that is variable within 19 the literature. For me, chronic is 20 exposure -- if as a toxicologist, I would 21 typically say chronic use is years of use. 22 It doesn't have to be daily, but it would be 23 years. That's the most common description 24 you see in toxicology, so I would say that's 25 fair. That's a fair assessment of my</p>	<p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. Good afternoon again, 3 Dr. Plunkett. 4 A. Good afternoon. 5 Q. I want to talk a little bit 6 about the Health Canada assessment. 7 We talked about this before, 8 but this is something that you reviewed after 9 you completed your report which has been 10 marked as Exhibit 4, correct? 11 A. Yes, and I wanted to tell you, 12 I did not bring all those documents printed. 13 I apologize. So there is a separate Health 14 Canada draft risk assessment that I didn't 15 print. 16 Q. Okay. So when you're referring 17 to the Health Canada analysis, what document 18 are you specifically referring to? 19 A. So I'm referring to the -- the 20 combined documents, but there are times when 21 you've asked me questions that I've been 22 referring -- and I tried to say, I believe, 23 Taher. 24 But, yes, some of the questions 25 you asked me when I said Health Canada, I was</p>

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Page 202	Page 204
<p>1 talking about the combined documents, which</p> <p>2 would include their -- I guess it's called a</p> <p>3 draft risk assessment document, yeah, which</p> <p>4 refers to this document but is a separate --</p> <p>5 is their own separate statement.</p> <p>6 Q. As you sit here today, what is</p> <p>7 your understanding of the current position</p> <p>8 that has been articulated in the collection</p> <p>9 of documents that you refer to as Health</p> <p>10 Canada with respect to any potential</p> <p>11 relationship between cosmetic talc and</p> <p>12 ovarian cancer?</p> <p>13 A. So that's why I did print out</p> <p>14 the small one, because I think it summarized</p> <p>15 it. So here, if you look at this Exhibit 6,</p> <p>16 it makes specific conclusions or draws --</p> <p>17 makes statements. And essentially it talks</p> <p>18 about talc being a possible risk of ovarian</p> <p>19 cancer, but then it gives women specific</p> <p>20 advice about what to do in order to minimize</p> <p>21 exposure to the products, and some of that</p> <p>22 was relevant as well.</p> <p>23 Just one reason I printed it</p> <p>24 out, it has to do with either choosing an</p> <p>25 alternative product or avoiding genital</p>	<p>1 there is a association between those two</p> <p>2 things, the exposure and the response, which</p> <p>3 is more than a possible association, if you</p> <p>4 want to use those words.</p> <p>5 But my assessment that I've</p> <p>6 done is not exactly the same, for example, as</p> <p>7 IARC does, which is more of just a hazard</p> <p>8 assessment.</p> <p>9 Q. Right.</p> <p>10 So I'm focusing my questions</p> <p>11 now on your risk assessment as compared to</p> <p>12 the documents that you've supplied us with</p> <p>13 with respect to Health Canada. And if I</p> <p>14 understand it correctly, are you stating that</p> <p>15 your opinion with respect to the relationship</p> <p>16 between cosmetic talc and ovarian cancer, you</p> <p>17 believe that it is an association that is</p> <p>18 stronger than a possible risk; is that</p> <p>19 correct?</p> <p>20 A. Well, I don't say it's a</p> <p>21 possible risk; I say there is an increased</p> <p>22 risk. So I think it's a different statement,</p> <p>23 yes, absolutely.</p> <p>24 Of course, I'm not Health</p> <p>25 Canada, so, you know, they have a framework</p>
Page 203	Page 205
<p>1 exposure to talc.</p> <p>2 And let me see the exact words</p> <p>3 that they use, but --</p> <p>4 Q. Before you do that, do you</p> <p>5 agree with the characterization that cosmetic</p> <p>6 talc presents a possible risk of ovarian</p> <p>7 cancer?</p> <p>8 A. No, I don't think that's my</p> <p>9 opinion. I think my opinion is stronger than</p> <p>10 that.</p> <p>11 But are you talking about my</p> <p>12 causation analysis opinion or just my risk</p> <p>13 assessment opinion?</p> <p>14 Q. I'm asking about any opinion</p> <p>15 you intend to offer in the MDL.</p> <p>16 A. Okay. So I will not be giving</p> <p>17 the causation analysis opinion, so that -- I</p> <p>18 will take that off the table.</p> <p>19 So I think my opinion is a</p> <p>20 little stronger because I say that the</p> <p>21 exposure to the perineal -- the talc by</p> <p>22 perineal application in women increases the</p> <p>23 risk. So I'm not saying it's a possible</p> <p>24 risk. I'm actually -- I believe that it</p> <p>25 increases the risk. And I do believe that</p>	<p>1 upon which they make decisions, and I'm doing</p> <p>2 an analysis based on what I have done. And</p> <p>3 so it's not exactly the same, although some</p> <p>4 of the same documents and information is</p> <p>5 weighed within -- and then that's when you</p> <p>6 have the issue of what Health Canada does</p> <p>7 versus what they rely upon.</p> <p>8 But this Taher risk assessment</p> <p>9 is just one piece of information that Health</p> <p>10 Canada has weighed in their assessment if you</p> <p>11 read their -- their draft risk assessment.</p> <p>12 Q. So the question I have about</p> <p>13 the Taher risk assessment, earlier you were</p> <p>14 referring to the fact that you have only seen</p> <p>15 a quantitative assessment of the weight of</p> <p>16 particular components of scientific evidence</p> <p>17 in evaluating epidemiological studies; is</p> <p>18 that correct?</p> <p>19 A. So that's what I typically see,</p> <p>20 yes. And I don't know that -- I've never</p> <p>21 seen it. But the typical approach would be</p> <p>22 to use it there as opposed to using it in the</p> <p>23 context of a human health risk assessment</p> <p>24 based on animal in vitro data.</p> <p>25 Q. All right. Are you familiar</p>

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Page 206	Page 208
<p>1 with something called the Klimisch scoring 2 system? 3 A. I don't know if I am now. 4 You'll need to show me what it is you're 5 referring to. The name doesn't ring a bell, 6 no. 7 Q. Okay. So it's not something 8 that you've used in the past? 9 A. No, not that I recall using. 10 Q. All right. 11 A. Unless it has another name, and 12 that's why I'm asking you. 13 Q. All right. So if you have 14 actually -- it's the document in front of you 15 that we've already marked as Deposition 16 Exhibit 5, I believe. 17 A. Yes. 18 Q. And that is the Taher study 19 that we were discussing and is cited by the 20 Health Canada risk assessment. 21 If you turn to page 5 -- well, 22 actually beginning on page 4, do you see 23 there is a section entitled "Literature 24 Search and Identification of Relevant 25 Nonhuman Studies"?</p>	<p>1 So, yes, if they stated they've 2 done -- we'd have to pull the supplementary 3 materials out, but I recall them doing 4 scoring based on epi studies but not on 5 the -- all of the animal studies that they 6 talk about. But we can pull it out and look. 7 I could be wrong. 8 Q. Okay. Did you review the 9 supplementary material 7, 8 and 9? 10 A. Yes, I did, and we'd have to 11 pull them out because I don't recall the 12 details. 13 Q. All right. We may take a look 14 at those in a minute. 15 It talks about them classifying 16 the animal and in vitro studies into four 17 categories of reliability. 18 Do you see that? 19 A. Yes. 20 Q. So did you make any attempt, 21 when you were reviewing the various studies 22 in reaching your opinion about the potential 23 risk of talc in causing ovarian cancer, did 24 you make any attempt to separate out the 25 different pieces of evidence into categories</p>
Page 207	Page 209
<p>1 Do you see that? 2 A. Yes. 3 Q. And this is related to an 4 analysis that these authors performed on 5 potentially relevant animal and in vitro 6 studies, correct? 7 A. Yes, that is true. 8 Q. All right. And it states here 9 that "all retrieved studies were examined for 10 relevance, reliability and overall quality 11 using the Klimisch scoring system." 12 Do you see that? 13 A. Yes, I do see that. So I have 14 seen that before. I just didn't -- I didn't 15 recall it. 16 Q. Okay. And so would you agree 17 that it is possible and in fact has been done 18 in a study that you rely on to apply a 19 quantitative scoring system to animal and in 20 vitro studies, particularly in the context of 21 looking at the relationship between talc and 22 ovarian cancer? 23 A. Well, I didn't say it was 24 impossible. I said I don't believe it's 25 routine based on my experience.</p>	<p>1 of reliability like the authors of this paper 2 have done? 3 A. I didn't do it exactly the way 4 they did it, but I certainly do do that as 5 part of my screening. 6 I told you one of the 7 characteristics or one of the assessments I 8 make is whether I believe the data is 9 reliable data that I can -- that I can use in 10 a weight of the evidence. So I make a -- and 11 when I talk about reliability, I'm talking 12 then about things such as I mentioned, peer 13 review, whether or not there is statistical 14 analysis, whether or not the study is 15 designed in a way that's consistent with 16 general principles of toxicology, control 17 groups or not control groups. 18 Those kinds of things I do -- I 19 do consider when I am assessing the use of a 20 study or not. 21 Q. Is it your testimony here today 22 that contained within your report that's 23 marked as Exhibit 4, I could find 24 categorization of reliability of each of the 25 pieces of scientific literature that you have</p>

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Page 210	Page 212
<p>1 included in your weight of the evidence 2 analysis? Is that your testimony today? 3 A. No, that's not what I'm telling 4 you, no. 5 Q. Okay. So you would agree that 6 you did not -- first of all, did you develop 7 categories of reliability in which you 8 separated the particular scientific studies 9 into as part of your weight of the evidence 10 analysis? 11 A. I do look at -- I do categorize 12 studies based upon my assessment of their 13 reliability and their ability to be used to 14 answer the question I'm asking, but I -- I 15 already told you, I didn't do it the way it's 16 set out here. I didn't have these specific 17 five categories, no. That's not what I did. 18 Q. Okay. Other than the CIR 2013 19 publication, which you have said that you do 20 not find reliable and you assign little 21 weight to it, can you point me to another 22 place in Exhibit 4 where you assign a 23 specific category of weight that you have 24 given to a particular study that you include 25 in your weight of the evidence analysis?</p>	<p>1 reliance list? 2 A. I believe it was, yes. 3 Q. Okay. And so for this one I 4 just want to direct your attention to the 5 conclusion section -- well, let me ask you 6 first: How does this document relate to the 7 collection of documents with respect to 8 Health Canada that you identified as relevant 9 to your opinion? 10 A. It was one of the materials 11 that they rely upon or they cite. That's the 12 reason I pulled it. It was -- I pulled 13 documents that they provided on the website 14 that were cited. 15 Q. Okay. And if you could turn to 16 page 11 of that document, there's a 17 conclusion section. The first sentence of 18 the third paragraph reads, "The given -- 19 given the context-specific nature of each 20 risk assessment and the diversity of tools 21 and criteria applicable, transparent 22 documentation of the specific application of 23 the WOE approach is especially important." 24 Did I read that correctly? 25 A. Yes, you did.</p>
Page 211	Page 213
<p>1 A. If what you're asking me is do 2 I make a specific statement next to each 3 study that I discuss about little weight or 4 great weight, no, I don't do that, if that's 5 what you're asking me. 6 Q. Okay. As part of the 7 collection of documents that relate to Health 8 Canada that was provided to us as part of 9 your new reliance list, did you review a 10 document entitled weight of the evidence -- 11 or "Weight of evidence: General principles 12 and current applications of Health Canada"? 13 A. Yes, I've seen that. 14 (Plunkett Exhibit 8 marked for 15 identification.) 16 QUESTIONS BY MS. BRANSCOME: 17 Q. All right. We will mark this 18 as Plunkett Deposition Exhibit Number 8. 19 All right. The document that I 20 just handed you that's marked as Plunkett 21 Deposition Exhibit Number 8, are you familiar 22 with that document, Dr. Plunkett? 23 A. Yep, I've seen this before. 24 Q. Is this listed among the new 25 materials that have been added to your</p>	<p>1 Q. And is your understanding of 2 WOE that it is weight of evidence? 3 A. Yes, that's correct. 4 Q. Do you agree with this 5 statement? 6 A. In a regulatory context, I do 7 believe that that is true, because within the 8 regulatory context when they do the risk 9 assessment, there's a need to understand why 10 decisions are made. So, absolutely, in a 11 regulatory context, I would agree that this 12 kind of transparency is even being adopted by 13 EPA. 14 Q. And is it your opinion then 15 that a different level of transparency is 16 needed for expert testimony in court? 17 A. No, that's not what I'm saying. 18 I'm saying that's a different process. And 19 that's what part of this process is. It's 20 understanding the ability to provide a dialog 21 about what was done. 22 So as a result, this is 23 something that is common to the work that 24 I've done in the past. Even in a 25 nonlitigation context with my regulatory</p>

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Page 214	Page 216
<p>1 clients, doing a risk assessment doesn't 2 necessarily involve the same level of detail 3 that a regulatory -- a regulator would apply 4 to the transparency of the assessment. Not 5 to say that it couldn't be done, but it's 6 just -- I would say it's not necessarily 7 typical. 8 Q. So this specifically refers to 9 transparent documentation. 10 Do you see that? 11 A. Yes. 12 Q. Would you agree that the report 13 that you have produced in the MDL does not 14 have documentation of the specific 15 application of the weight of evidence 16 approach? 17 MS. PARFITT: Objection. 18 Excuse me, objection. Form. 19 THE WITNESS: I disagree to an 20 extent because I did attempt to 21 provide in my report a description of 22 the methods that I used and the 23 resources that I've relied upon for a 24 discussion of how those methods are 25 used.</p>	<p>1 study. In other words, as I discussed many 2 times in deposition, when you're talking 3 about doing a human health risk assessment, 4 there's certain types of data that are most 5 relevant. I mean, when they use the word 6 "reliable" -- I don't know that many of these 7 studies have the same level of reliability as 8 far as peer review, but they're -- for 9 example, on the issue of migration, it's my 10 opinion that the data from the human studies 11 is a more reliable or relevant source of 12 information. And I've laid out why, because 13 of differences in the anatomy, things like 14 that, with the data. 15 Q. Are you familiar with the term 16 "binning exercise"? 17 A. Yes, I am. And that is 18 certainly something that I have used in other 19 aspects of work that I have done. 20 Q. Did you do a binning exercise 21 in rendering your opinions and what you've 22 provided to us in the context of your 23 opinions in the MDL? 24 A. Yes, that's the exercise I 25 start with. I'm binning them into human,</p>
Page 215	Page 217
<p>1 And then in addition to that, 2 I've attempted to lay out for you in 3 my report a discussion of the pieces 4 of evidence that I've relied upon, 5 including some -- for some of those -- 6 that's one of the reasons I got so 7 detailed in the section on migration 8 and providing you an analysis of each 9 of the papers that I relied upon and 10 what I thought was important within 11 them that led to my -- the formation 12 of my opinions. 13 So I disagree to some extent. 14 QUESTIONS BY MS. BRANSCOME: 15 Q. Okay. Turning back to what 16 Taher did in classifying different studies 17 into different categories of reliability. 18 Have you done that type of analysis in the 19 past where you have separated out different 20 studies into different categories of weight 21 or reliability as part of an overall 22 analysis? 23 A. Well, I do that every time I do 24 a weight of the evidence when I separate into 25 categories first based upon the type of</p>	<p>1 animal, mechanistic, in vitro data. That's 2 the first bins. 3 In fact, in the copper work we 4 did, that's what we did. We separated the 5 data into in vitro/only mechanistic 6 information, animal studies, did we have 7 human studies. 8 And we also looked at 9 studies -- we had a separate bin of exposures 10 like I do. I have studies that just address 11 the issue of exposure potentially. 12 So, yes, it's -- it's 13 consistent with doing that. It's -- 14 essentially binning is just separating the 15 information into groups based on what 16 questions those -- those data can answer. 17 Q. Okay. Have you ever -- do you 18 ever separate them into bins based on the 19 level of weight that you would give a 20 particular study? 21 A. I do that when I'm analyzing 22 each of the studies within that group or that 23 bin. That's what I do. I give them -- in my 24 weight -- in my analysis, I weigh those 25 studies based upon my judgment on the</p>

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<p style="text-align: right;">Page 218</p> <p>1 relevance, the reliability, the power of the 2 study, the statistical analysis that's done, 3 the inclusion in animal studies, in 4 particular, of controls. Those are all parts 5 of that analysis that I do. So, yes, I do do 6 that. 7 And then in -- there have been 8 exercises that I've done in the past with 9 other individuals where we may have taken a 10 yellow sticky note and put down on top of it 11 animal data with exposure information, animal 12 data without exposure information. That's 13 the process that I'm doing when I am looking 14 across the data. I'm separating those pieces 15 of data into groups and what types of 16 questions they can answer. 17 So that is consistent with what 18 I do when I do a weight of analysis approach 19 in the work that I do in both nonlitigation 20 and litigation context. 21 Q. Okay. But we have no specific 22 documentation of the different ratings that 23 you gave the various pieces of evidence that 24 you included in your weight of the evidence 25 analysis, aside from occasional references to</p>	<p style="text-align: right;">Page 220</p> <p>1 inflammation, cause ovarian cancer? 2 A. Because it doesn't change the 3 phenotype of the cell. It has to -- the -- 4 and I discuss that. You have to -- you have 5 to set up a chronic inflammatory process that 6 leads to changes within the cellular 7 phenotype to go from a cell that is -- that 8 is -- is dividing normally to a cell that 9 isn't. 10 So it's -- it's the same issue 11 that you address even in a study in animals. 12 Why do not all animals exposed to -- exposed 13 to a chemical develop tumors. It's the idea 14 that something has to be initiated beyond the 15 exposure or maybe beyond inflammation to lead 16 to the series of events. 17 And so, yes, it's recognized 18 that you can get inflammation, and 19 inflammation can go down the road in becoming 20 a carcinogenic process, or inflammation can 21 no longer -- can stay where it is. It 22 doesn't progress beyond just a chronic 23 inflammatory process. 24 Q. And so if you had a study that 25 demonstrated that a particular agent causes</p>
<p style="text-align: right;">Page 219</p> <p>1 giving something less or more weight, 2 correct? 3 A. Well, I certainly -- I told you 4 I have not given numerical values that you're 5 asking me, but I've attempted to do that when 6 I have described them in groups, when I talk 7 about human versus animal versus in vitro. 8 Because I've already told you, I believe, 9 it's my opinion that certain types of 10 information are more informative than others. 11 And so the more informative it is, the more 12 weight you're giving it in -- obviously in 13 your analysis. 14 But it is a different exercise 15 than what is described here. And here I'm 16 pointing to Exhibit 8. And it's a different 17 exercise, obviously, than what a regulatory 18 body is required to do where they are trying 19 to come up with ways to increase the 20 transparency when no one can go and actually 21 talk to each of the regulators individually 22 to understand what their thinking was. 23 Q. Okay. Returning to biological 24 mechanism for a minute, why doesn't 25 inflammation generally, including chronic</p>	<p style="text-align: right;">Page 221</p> <p>1 inflammation, you would need more information 2 in order to make the conclusion that that 3 agent can in fact cause cancer, correct? 4 MR. MEADOWS: Objection. 5 THE WITNESS: You would look 6 for more informative information, 7 exactly, which is why, when I've 8 talked about the individual 9 constituents in the context of 10 consistency on mechanism for cancer, 11 I've pointed to documents where that 12 information has been discussed. 13 So like when I talk about 14 asbestos or cobalt or I point to 15 the -- for example, the IARC 16 assessment where they go through 17 that -- that discussion of the fact 18 that there's not just data showing 19 that a biologically plausible 20 mechanism may be inflammation, but 21 there's also data to show that that 22 can lead to tumor development as well. 23 QUESTIONS BY MS. BRANSCOME: 24 Q. Okay. How does talc change the 25 phenotype of the ovarian cell?</p>

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Page 222	Page 224
<p>1 A. So this is one of the details 2 we don't know, other than generally it's 3 changing the phenotype to go from a normal 4 cell to a tumor cell. That is being 5 observed. When you find the presence of the 6 tumor, that is what you're observing. 7 Q. Does pure talc with no other 8 constituent components, can it change the 9 phenotype of an ovarian cell? 10 MR. MEADOWS: Objection. 11 THE WITNESS: So that's a 12 difficult question to answer with 13 certainty because of the fact that I 14 don't believe that we have assurance 15 that any of the studies are done with 16 essentially pure talc. 17 However, in the studies that 18 claim to have been done with pure 19 talc -- for example, the NTP study 20 claims to have been done with pure 21 talc. So if that is pure talc, truly 22 is, then that study is an example of 23 evidence for the chronic inflammatory 24 process leading to preneoplastic 25 lesions that are setting down the road</p>	<p>1 in vitro or an animal experiment -- by which 2 you would expose either cells or animal to 3 talc with different constituent products to 4 identify or separate out the individual 5 effects of the components? Is that a study 6 that you could design as a toxicologist? 7 A. I think that would be difficult 8 to do, but I'm not saying impossible to do. 9 And here's the -- there are some very 10 specific considerations you'd have to put 11 into that design. 12 I would argue that some of that 13 is already available, where we have studies 14 that have looked at the dose-response effects 15 for toxicity with cobalt, with chromium, with 16 asbestos. 17 When you get to asbestos and 18 talc, it's more problematic because then the 19 question is what is -- what is it? What are 20 the specific characteristics in all the 21 different studies of exactly what the 22 asbestos was versus exactly what the talc 23 was. 24 But I think you could attempt 25 to do that, and then the question would be,</p>
Page 223	Page 225
<p>1 mechanism towards cancer. 2 So there are data out there. 3 The problem you have, I believe, in 4 the literature is whether or not, 5 based on the discussion that is 6 becoming apparent now with sensitivity 7 and ability to take the natural 8 product and actually determine exactly 9 what's in it, that I don't think there 10 is the ability to assure that any -- 11 any of these studies with the samples 12 of talc they're using is absolutely, 13 100 percent, only platy talc. I think 14 there's -- there's some concern about 15 that. But certainly you will take -- 16 you have to take what is discussed 17 within the study as evidence from what 18 they're claiming. 19 So many of the studies say we 20 used asbestos-free talc or platy -- 21 pure platy talc and we got a toxic 22 response. 23 QUESTIONS BY MS. BRANSCOME: 24 Q. Would it be possible to design 25 an experiment -- and now I'm talking about an</p>	<p>1 being able to use that data not so much to -- 2 not so much to identify a dose response for a 3 certain insult, but to look at the fact -- 4 look at potency differences across the 5 compounds. And then there's the issue of 6 then looking at additivity when you know you 7 have a complex mixture. 8 So that could be done, but, 9 again, it would be difficult to do based on 10 what we know about talc, being able to really 11 know that -- you would have to really be very 12 careful that what it is that you're looking 13 at is -- is not containing any of those 14 things that we unfortunately know co-occur 15 with constituents within the natural product. 16 But no one has done those 17 studies. I point that out. I haven't seen 18 that study that you're asking for. I have 19 not seen somebody do that. 20 Q. And a study like that would be 21 relevant in evaluating the potency of the 22 individual constituents and what might 23 actually be the driving factor for phenotypic 24 change, correct? 25 A. Not necessarily. I would argue</p>

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Page 226	Page 228
<p>1 that we already have an answer to that by 2 looking at the data that's been collected on 3 the complex mixture itself. So the issue 4 would be why -- the question is what do you 5 gain by being able to say that we're only 6 pointing to this constituent or that 7 constituent. That isn't what is occurring. 8 What people are exposed to is 9 the complex mixture, not just each one of 10 those individual components. To me this is 11 not a case of asbestos-only exposure. This 12 is a case of exposure to consumer products 13 that are talc that may have within them at 14 any given time -- and data indicates that 15 there are substantial chance that asbestos 16 may be in -- is in certain of these products. 17 But my opinions are not 18 dependent on there being asbestos there at a 19 particular level or copper there -- or, I'm 20 sorry, cobalt there at a particular level 21 because my opinions are based on the 22 observations we have on the complex product 23 as it exists. 24 Q. And you recognize that 25 different types of talc and different talc</p>	<p>1 been linked to an inflammatory response. 2 Oxidative stress is often a triggering 3 mechanism. 4 Q. Does the body have protective 5 mechanisms that limit tissue damage from 6 oxidative stress? 7 A. Yes, which is why not everybody 8 that's exposed to any particular chemical is 9 going to get cancer. Some people will 10 respond better. Some cells will respond 11 better. Some individuals in a population at 12 one time in their life may respond better. 13 Q. You would agree that in vitro 14 studies do not account for the body's natural 15 defenses outside of what exists at the 16 cellular level, correct? 17 A. Depends on the in vitro study 18 that's being done and whether or not there is 19 components added. 20 So I've seen studies done where 21 they take cells and then add extra levels of 22 glutathione to try to protect the cells from 23 certain stressors that could lead to damage, 24 but I agree with you that an isolated cell on 25 its own is a different microenvironment than</p>
Page 227	Page 229
<p>1 products have different constituent 2 components in different amounts, correct? 3 A. Some can. I agree with that. 4 That is true. 5 So if you're being broad, as in 6 pharmaceutical-grade versus industrial-grade 7 or chemical-grade, yeah, because they'll have 8 a purity level assigned. 9 But as far as what the -- what 10 the components are, it isn't always defined 11 even specifically within that. 12 Q. Okay. And does the presence of 13 oxidative stress in a tissue indicate that 14 cancer will develop in that tissue? 15 A. Will definitively develop? 16 Not -- I don't think you could say 17 definitively develop, but it's certainly in 18 the biologically plausible mechanism that's 19 been understood to lead to chronic 20 inflammation and also has been linked to 21 cancer. 22 So that's the issue of not 23 necessarily saying it has to be there, but it 24 certainly is something that is observed 25 routinely in cases where carcinogenesis has</p>	<p>1 an intact tissue, which is a different 2 environment than an intact animal, which is 3 even different than an intact human being. 4 Yes, they're all -- you look at those levels 5 of evidence or those types of evidence 6 differently, depending upon the end points 7 you're collecting. 8 Q. And so you would give lower 9 weight to an in vitro study as compared to an 10 in vivo study, for example? 11 A. Depends on the question you're 12 asking. I would give a lot of weight if the 13 question is what do I know -- if I want to 14 try to understand the biologically plausible 15 mechanism, some of those in vitro studies are 16 some of the most important, because it's the 17 only ones that allow us to answer a question. 18 If the question is higher level 19 about what is the evidence to show that 20 there's an increased risk overall for cancer 21 or a hazard for cancer, then certainly you 22 need to have more than an in vitro study. 23 So as -- so on -- if you want 24 to layer it up, obviously, if all you had was 25 in vitro data, you'd have much less</p>

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<p style="text-align: right;">Page 230</p> <p>1 confidence in the conclusions you can draw 2 unless you had some in vivo data. In vivo 3 data is going to allow you to interpret the 4 in vitro data. 5 So certainly there would be 6 more weight given in that assessment to the 7 fact that you had in vivo data. 8 Q. And so when you made the 9 statement that, for instance, you always give 10 more weight to human data, is that true, or 11 does that also depend? 12 A. Well, it depends on whether you 13 have human data. So if I have human data and 14 I have a doubt, any doubts at all, about 15 whether or not the exposure-response 16 relationship would be affected by the way the 17 animal studies are designed, then, yes, I 18 would give more weight to the human studies. 19 In a case, however, such as 20 inhalation exposure assessments where 21 there -- it's much better, actually, to do an 22 animal study where we can do a dose response 23 across different sizes of particles and 24 actually observe lesions as they develop over 25 time, which is why I love -- I love the NTP</p>	<p style="text-align: right;">Page 232</p> <p>1 weight, but it could if you only had one 2 crappy human study, one really badly designed 3 human study, and I had a GLP quality cancer 4 bioassay then, absolutely. I mean, IARC does 5 this. They look at that animal data and say, 6 "This one tells us -- answers the questions 7 we want to answer, and this very poorly 8 designed case series isn't going to allow us 9 to do that." 10 So you could, but I would say 11 it's more the other issue, that you look at 12 animal and human more on an equal basis if 13 the relevance and the extrapolation can be 14 done reliably. 15 And that's the question you 16 have to ask, can I extrapolate from animals 17 to humans in a reliable manner. 18 Q. Okay. Would you agree that the 19 response to cosmetic talc can vary depending 20 on tissue type in the body? 21 A. Yes, I would say that that is 22 true, whether or not there's certain 23 protective barriers in place, for example, 24 yes. 25 Q. And so in order to draw</p>
<p style="text-align: right;">Page 231</p> <p>1 93 study of interim sacrifices, looking at 2 that issue. That data is very reliable in 3 order to understand the risk of lung damage 4 as compared to a human study where we don't 5 have those serial time points, doses that are 6 defined tightly. 7 So -- and the relevance between 8 those kinds of initial lung injury in certain 9 animals versus humans match fairly well. 10 That's my problem, though, in 11 the case with the perineal exposure. I'm 12 saying to you, because of the route of 13 contact -- we need to be able to get it there 14 to the tissue -- the human data is extremely 15 important. 16 Q. So is it fair to say that in 17 some circumstances animal data gets more 18 weight than human data and in other 19 circumstances human data gets more weight 20 than animal data? It is circumstance 21 dependent? 22 A. I would put it a different way. 23 I would say in some cases animal data is 24 weighted in a similar manner to human data. 25 I don't necessarily say it would get more</p>	<p style="text-align: right;">Page 233</p> <p>1 conclusions based on a study of one cell 2 type's reaction to cosmetic talc to another, 3 you would need to understand the differences 4 in similarities between those two cell types, 5 correct? 6 MS. PARFITT: Objection. 7 THE WITNESS: It's a different 8 question. So you were asking me 9 about -- I didn't think you were just 10 asking about cells. I thought you 11 were asking me about like routes of 12 exposure, dermal versus inhalation. 13 Those things differ. 14 Cell types may or may not. 15 That may or may not be true. Because 16 if two cells -- two different cell 17 types in the body share similar 18 characteristics as far as the -- for 19 example, if they're both epithelial 20 cells or mesothelial cells, those type 21 of cells you would expect to respond 22 the same way. 23 But I would agree that, for 24 example, a neuronal cell versus a GI 25 cell versus a liver cell, there could</p>

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Page 234	Page 236
<p>1 be differences in how they would</p> <p>2 respond, yes, and so you would -- you</p> <p>3 would look at those things</p> <p>4 individually.</p> <p>5 QUESTIONS BY MS. BRANSCOME:</p> <p>6 Q. And so it's important to</p> <p>7 understand the differences and the</p> <p>8 similarities between the different cell types</p> <p>9 before drawing conclusions using studies from</p> <p>10 different cell types?</p> <p>11 MS. PARFITT: Objection.</p> <p>12 MR. MEADOWS: Objection.</p> <p>13 THE WITNESS: I certainly think</p> <p>14 you should consider the cell types</p> <p>15 that are being used and whether or not</p> <p>16 those cell types are ones that are</p> <p>17 relevant to your risk assessment</p> <p>18 question you're asking, yes.</p> <p>19 QUESTIONS BY MS. BRANSCOME:</p> <p>20 Q. Okay. You would agree as a</p> <p>21 toxicologist, dose is an important part of a</p> <p>22 toxicological analysis of an agent, correct?</p> <p>23 A. If you're doing risk, yes. If</p> <p>24 you're only doing hazard, it may not be as</p> <p>25 important. It depends upon the question</p>	<p>1 Q. Okay. And in your -- in your</p> <p>2 report, as part of your risk assessment that</p> <p>3 you did in the MDL -- this is paragraph 12 on</p> <p>4 page 8.</p> <p>5 A. Yes, I'm there.</p> <p>6 Q. Okay. You state about</p> <p>7 two-thirds of the way down the paragraph that</p> <p>8 "weight of the evidence methods were critical</p> <p>9 to defining the literature that identified</p> <p>10 the hazards of talc exposure as well as</p> <p>11 defining the dose-response relationship</p> <p>12 between talc exposure and the risk of adverse</p> <p>13 health effects."</p> <p>14 Did I read that correctly?</p> <p>15 A. You did. That's correct.</p> <p>16 Q. All right. Is it your view</p> <p>17 that in the case you have reached an opinion</p> <p>18 that defines the dose-response relationship</p> <p>19 between talc exposure and the risk of ovarian</p> <p>20 cancer?</p> <p>21 A. It depends what you mean by</p> <p>22 define. I can tell you what I mean in this</p> <p>23 sentence, and maybe that would help you.</p> <p>24 Q. Dr. Plunkett, it is your</p> <p>25 report. And so I am asking you, using your</p>
Page 235	Page 237
<p>1 you're asking about hazard.</p> <p>2 Do you want me to explain?</p> <p>3 Q. I do want you to explain the</p> <p>4 difference between a risk analysis and a</p> <p>5 hazard analysis.</p> <p>6 A. Okay. So in an initial hazard</p> <p>7 analysis, if the question is, is there a</p> <p>8 hazard associated with exposure, let's say,</p> <p>9 by inhalation, it may not matter whether it</p> <p>10 was a high dose or a low dose study. Both of</p> <p>11 those can identify hazard.</p> <p>12 Then you ask the question: Is</p> <p>13 there a dose-response relationship? That's</p> <p>14 the next step beyond hazard.</p> <p>15 So hazard is -- to me is</p> <p>16 identifying the end points that you're going</p> <p>17 to monitor for toxicity, sort of the target</p> <p>18 organs, those things, and so whether or not</p> <p>19 there's a dose-response study available, it</p> <p>20 wouldn't be as important.</p> <p>21 But certainly when you go to</p> <p>22 that next step to assess risk, you'd like to</p> <p>23 be able to see whether or not there is a</p> <p>24 dose-response relationship in the effect that</p> <p>25 you're assessing.</p>	<p>1 own definition of "define," have you rendered</p> <p>2 an opinion that defines the dose-response</p> <p>3 relationship between talc exposure and the</p> <p>4 risk of ovarian cancer?</p> <p>5 A. I have formed opinions about</p> <p>6 the dose-response relationship generally, but</p> <p>7 unfortunately -- I answered that question for</p> <p>8 you earlier when you asked me, I think, about</p> <p>9 is there -- I don't know if you used the word</p> <p>10 "threshold," but I did.</p> <p>11 So the available information</p> <p>12 doesn't allow us to identify an ultimate</p> <p>13 threshold, for example, in the case of women</p> <p>14 exposed to talc perineally and their -- and</p> <p>15 their development of ovarian cancer.</p> <p>16 Instead, in defining the dose</p> <p>17 response, what we can do with the data -- and</p> <p>18 that is what I attempted to do. This is</p> <p>19 where you look at defining the dose response</p> <p>20 in the animal studies, which we can look at,</p> <p>21 or defining dose response in cell studies,</p> <p>22 showing that as the dose increases, the</p> <p>23 hazard and the risk increase. So risk</p> <p>24 actually you quantify. There's a certain</p> <p>25 response at this dose and a different</p>

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<p style="text-align: right;">Page 238</p> <p>1 response at the next dose, or have we 2 plateaued, that the responses are the same as 3 dose increases. 4 So that, I did do that as part 5 of my assessment, trying to define the dose 6 as far as how that linked to the responses in 7 each of the studies I looked at. 8 Q. You would agree, though, that 9 some studies did not show a dose relationship 10 between talc and ovarian cancer or the 11 clinical signs that were indicative of the 12 potential for development into ovarian 13 cancer, correct? 14 MS. PARFITT: Objection. 15 THE WITNESS: If you're talking 16 about the human data; is that what 17 you're referring to? Or are you 18 talking about all -- any of the data? 19 QUESTIONS BY MS. BRANSCOME: 20 Q. Any of the data. 21 A. So I would disagree on the 22 animal data. I think on the animal data they 23 often -- most of the animal studies I've 24 relied upon have looked at more than one dose 25 or at least looked a no exposure versus a</p>	<p style="text-align: right;">Page 240</p> <p>1 or -- that they may make a -- an 2 author may make a statement, but I'm 3 talking about looking -- this is 4 weight of the evidence. I'm looking 5 across. And I'm saying, across the 6 data, when I look at the human data 7 versus the animal data, for example, 8 versus in vitro studies, the in vitro 9 studies and the animal studies allow 10 you to look at dose response for talc 11 toxicity. 12 The -- even the animal studies 13 allow you to look at dose response for 14 development of precancerous lesions, 15 you're on the way to cancer, for 16 example, in the NTP studies. 17 And then in the human studies, 18 some of those studies are designed 19 such that the authors could draw 20 conclusions about dose response and 21 some are not. 22 Even in some of the studies 23 where they attempted to look at dose 24 response, some of the authors indicate 25 they don't see an effect. So that is</p>
<p style="text-align: right;">Page 239</p> <p>1 dose, and most of them have looked at more 2 than one dose. 3 In the case of the human 4 studies, unfortunately, some of those studies 5 were not designed to be able to define dose. 6 In other words, the questions weren't asked, 7 for example, of the individuals even in the 8 prospective studies. Some of those 9 included -- did not include the information 10 collected on frequency and duration of use. 11 So if it's not collected, 12 obviously, I don't have it to look at. And 13 that's one of the limitations of human 14 epidemiological investigations, is that it 15 often is not designed appropriately to look 16 at dose response. 17 Q. Is it your opinion that there 18 are no studies looking at talc and the risk 19 of ovarian cancer in which the authors of the 20 study have concluded there was no clear 21 pattern of increased risk with dose? 22 MS. PARFITT: Objection. 23 THE WITNESS: No, that's not 24 what I've said. No. It's very 25 possible that an individual paper</p>	<p style="text-align: right;">Page 241</p> <p>1 true. And part of that may be driven 2 by the design of the study, the number 3 of individuals in the study, the way 4 that the questions were asked. 5 There's limitations on the way that 6 information is collected. 7 If you want to look at each 8 study, we can, but -- 9 QUESTIONS BY MS. BRANSCOME: 10 Q. So my question to you, whether 11 you agree or disagree with the author's 12 conclusion, is simply that if you look at the 13 overall animal and human studies that you 14 cite in your report or have considered on 15 your reliance list that look at a potential 16 dose-response relationship for talc toxicity, 17 do some of those studies conclude that there 18 is not a dose-response relationship? 19 MS. PARFITT: Objection. 20 THE WITNESS: I disagree for 21 talc toxicity, but I would say if 22 you're going to limit it to the issue 23 of the ovarian cancer response, I 24 would agree. I have seen that in some 25 of the studies.</p>

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Page 242	Page 244
<p>1 I think talc toxicity, I don't</p> <p>2 know if anybody has made the</p> <p>3 comment -- I would doubt it -- that</p> <p>4 there is no dose response for toxic</p> <p>5 effects of talc.</p> <p>6 QUESTIONS BY MS. BRANSCOME:</p> <p>7 Q. Okay. You discuss in your</p> <p>8 report -- wait a moment. It's in</p> <p>9 paragraph 58 on page 38. And I just want to</p> <p>10 make sure I understood what you were citing</p> <p>11 here.</p> <p>12 In paragraph 58 you state that</p> <p>13 "It is important to remember that</p> <p>14 administration of even a single dose of talc</p> <p>15 in animals has been shown to produce adverse</p> <p>16 effects locally at the site of the exposure."</p> <p>17 What are you referring to</p> <p>18 there?</p> <p>19 A. Acute doses. In other words,</p> <p>20 in studies that have described installation</p> <p>21 of a single dose of talc in some form into a</p> <p>22 tissue, that they are observing adverse</p> <p>23 responses.</p> <p>24 An example of that may be</p> <p>25 the -- I think it's Hamilton. Is that the</p>	<p>1 is that you give them less weight because you</p> <p>2 believe that the individuals who conducted</p> <p>3 the study had been paid by either a company</p> <p>4 or agencies that had some investment in the</p> <p>5 outcome of the study; is that correct?</p> <p>6 A. Is that my opinion?</p> <p>7 Q. Yes.</p> <p>8 A. For any particular study,</p> <p>9 you'll need to show me what you're pointing</p> <p>10 to. I do have opinions about some of the</p> <p>11 work by Drs. Huncharek and Muscat, yes. I</p> <p>12 think I address that specifically, and that</p> <p>13 has -- that's not so much to do with my</p> <p>14 weight of the evidence; that has more to do</p> <p>15 with transparency and what was being</p> <p>16 disseminated to the public and disseminated</p> <p>17 to the FDA as far as evaluations.</p> <p>18 That's a different issue than</p> <p>19 the weight of -- the weight of -- the weight</p> <p>20 of the evidence assessment for risk. I think</p> <p>21 those were separate.</p> <p>22 Q. So then I'll ask you that.</p> <p>23 In doing your weight of the</p> <p>24 evidence analysis for risk, have you</p> <p>25 discounted the weight that you've given to</p>
Page 243	Page 245
<p>1 one where they stilled it into the ovaries</p> <p>2 with a single dose?</p> <p>3 Q. So these are large-dose</p> <p>4 exposures?</p> <p>5 A. Well, not all --</p> <p>6 Q. Or are they, I should say?</p> <p>7 A. I don't know that they all are,</p> <p>8 no. There are -- there are -- I don't think</p> <p>9 I have attempted to quantify large in this</p> <p>10 sentence.</p> <p>11 What I'm stating here is not an</p> <p>12 issue of large versus small. It's an issue</p> <p>13 of the fact that there are toxic effects with</p> <p>14 single exposures. And I'm just making the</p> <p>15 comment -- this has to do with hazard, right?</p> <p>16 It's the idea even a single dose -- or a</p> <p>17 single exposure you can get irritant,</p> <p>18 inflammatory reactions at the site of</p> <p>19 exposure. And that's all I'm trying to say.</p> <p>20 That's why I'm citing as reviewed by EPA. I</p> <p>21 believe EPA even makes a very similar</p> <p>22 statement.</p> <p>23 Q. Okay. Do you take into</p> <p>24 account -- there are some studies for</p> <p>25 which -- at least my reading of your report</p>	<p>1 any particular piece of scientific evidence</p> <p>2 based off of potential affiliations of the</p> <p>3 authors?</p> <p>4 A. I certainly did with the CIR</p> <p>5 review document. I've already told you that.</p> <p>6 And that's because I have evidence that shows</p> <p>7 it's not just an affiliation issue, but it's</p> <p>8 actually -- it's more -- it's more important</p> <p>9 than that.</p> <p>10 Q. Are there any other examples?</p> <p>11 A. I think that's the only one</p> <p>12 right now as I sit here that I can tell you</p> <p>13 that I had identified as carrying little</p> <p>14 weight because of an issue of either</p> <p>15 authorship or input in the way it was</p> <p>16 described.</p> <p>17 There are certainly studies</p> <p>18 within my weight of the evidence evaluation,</p> <p>19 some of which were performed by industry. I</p> <p>20 certainly look at that issue, but unless I</p> <p>21 have -- have a reason to believe that there's</p> <p>22 an inherent bias based on something I know,</p> <p>23 they go into the weight of the evidence</p> <p>24 without making a correction for that.</p> <p>25 In many cases that I work in</p>

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Page 246	Page 248
<p>1 litigation, I will find situations like the 2 situation here with Huncharek and Muscat 3 where I have, for example -- I think this 4 came up in the Risperdal litigation for me. 5 It's the idea that there was a series of 6 papers put out by an individual investigator 7 where documents that I could get access to 8 show me that indeed their analysis was not 9 done by them but it was ghostwritten by 10 somebody else. So that gives me pause, 11 although I would never have known that unless 12 I had access to internal documents. 13 So initial weight of the 14 evidence I did not discount it, but then I 15 went back and had to reevaluate the role 16 those studies played in my overall 17 assessment. 18 Q. Do you take into account in any 19 way in evaluating the weight of a study if it 20 is conducted by someone who serves as an 21 expert on behalf of the plaintiffs in the 22 active litigation? 23 A. It would be the same -- same 24 issue. I certainly consider it as part of 25 what I look at, but just like if they were an</p>	<p>1 tested, that he reports are Johnson's baby 2 powder, did you also consider the work that 3 was done by experts that have been retained 4 on behalf of the defendants to characterize 5 the components of Johnson's baby powder? Do 6 you give them equal weight? 7 A. So I haven't seen a variety of 8 the documents that you're talking about, 9 so -- because I have not worked in the 10 litigation cases that have involved asbestos 11 only. So -- which I think is where those 12 documents are. 13 In the litigation I -- in the 14 litigation I worked in, I am aware of what 15 other experts on both sides have said. I 16 don't believe I've seen an analysis from a 17 defense expert that is -- that is like 18 Dr. Longo's, at least in the litigation I've 19 worked in. Certainly I would consider that 20 and look at that if it's available, and I 21 would consider it. 22 I would point out, Dr. Longo's 23 analysis is not the piece of evidence that 24 you start with, though. You start with what 25 I discuss in the published literature first,</p>
Page 247	Page 249
<p>1 expert for the defense versus an expert for 2 the plaintiff, you judge that information 3 based on what you know. And if I don't have 4 information to discount it, I will not 5 discount it. 6 But absolutely, I understand. 7 Just as people we all -- look at some of the 8 things I've published where I have said my 9 work was sponsored by the American Chemistry 10 Council. You know, people -- that's why you 11 disclose the conflicts. You put it there so 12 people can weigh it if they want, but it 13 doesn't mean you discount the work 14 automatically. 15 And so I think for any paper, 16 plaintiff, defense, whoever it is that's 17 writing it, you need to consider it based on 18 the information you have. And if you believe 19 that you have information to indicate that 20 there's some issue with the reliability of 21 the analysis, then absolutely you consider 22 that. 23 Q. So, for example, when you rely 24 on Dr. Longo's characterization of the 25 constituent components in samples that he has</p>	<p>1 because there are published documents out 2 there in the literature that describe exactly 3 what Dr. Longo is now describing. 4 Q. What published documents are 5 those? 6 A. Those are Dr. Blount's reports 7 in 1991, which is before the litigation came 8 about, is my understanding. 9 There's also -- there's five or 10 six. I can tell you the paragraph. 11 Q. For Johnson's baby powder, I 12 would be interested in that, yes. 13 A. So I -- I'll have to look and 14 see if it's Johnson's baby powder only, but 15 certainly there is other evidence on the 16 issue of asbestos contamination and 17 specifically in talc. 18 So I -- you want me to find the 19 paragraph for you? 20 Q. Please. If you think there is 21 published literature documenting asbestos in 22 Johnson's baby powder, I would like to see 23 that. 24 A. So this is my paragraph 32. 25 And I'd have to pull each of these articles</p>

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Page 250	Page 252
<p>1 out because I don't recall what each of them</p> <p>2 says. But I'm pointing to Paoletti, Blount,</p> <p>3 Mattenklott, Moon, Gordon, Anderson, Rohl,</p> <p>4 Pooley and Rowlands, Blejer and Arlon,</p> <p>5 Cralley, Millman.</p> <p>6 And then I cite -- and then of</p> <p>7 course the next piece of evidence is there</p> <p>8 are actually documents from J&J and Imerys</p> <p>9 that show detection of asbestos or</p> <p>10 asbestos-like minerals in talc.</p> <p>11 Q. As you sit here today, can you</p> <p>12 identify which of these published articles</p> <p>13 that you list in paragraph 32 relate to</p> <p>14 Johnson's baby powder?</p> <p>15 A. I would have to pull them to</p> <p>16 answer that.</p> <p>17 Q. Okay.</p> <p>18 A. As I sit here, I'd have to pull</p> <p>19 them. But I would refer you -- I know at</p> <p>20 least some of them do based on the statement</p> <p>21 I've made, but...</p> <p>22 Q. So you did not make an attempt</p> <p>23 in this paper to identify which products were</p> <p>24 being analyzed in these specific articles.</p> <p>25 It's not indicated on the face of this</p>	<p>1 look.</p> <p>2 Q. Have you reviewed Dr. Blount's</p> <p>3 deposition?</p> <p>4 A. I have reviewed a -- something</p> <p>5 by Dr. Blount. Whether it was trial</p> <p>6 testimony or deposition, I have seen</p> <p>7 something, yes, that she has said regarding</p> <p>8 this issue.</p> <p>9 Q. To the extent that there is</p> <p>10 confusion about whether or not a sample</p> <p>11 tested by Dr. Blount is in fact Johnson's</p> <p>12 baby powder, would you reduce the weight that</p> <p>13 you give that particular piece of evidence in</p> <p>14 evaluating whether asbestos has been present</p> <p>15 in Johnson's baby powder?</p> <p>16 MS. PARFITT: Objection. Form.</p> <p>17 MR. MEADOWS: Objection.</p> <p>18 THE WITNESS: I don't know</p> <p>19 reduce the weight because -- because</p> <p>20 there's -- there are plenty of</p> <p>21 documents here that talk about that.</p> <p>22 I would consider it --</p> <p>23 certainly it would -- it's not so much</p> <p>24 weight. It's a different bin. We'll</p> <p>25 call it a bin, a different bin of</p>
Page 251	Page 253
<p>1 paragraph, correct?</p> <p>2 A. I don't tell you on the face,</p> <p>3 but you if read the sentence I said, "When</p> <p>4 commercially available, talcum powder</p> <p>5 products were analyzed, including powders</p> <p>6 sold by Johnson & Johnson. The data has</p> <p>7 shown that the powders contained varied</p> <p>8 levels" -- and I'm saying "fibers," so it's</p> <p>9 just asbestos -- "including fibers that</p> <p>10 stated to be asbestos."</p> <p>11 So to tell you which of those,</p> <p>12 I'd have to pull them. And I apologize, I</p> <p>13 didn't bring them all with me.</p> <p>14 Q. Have you been provided --</p> <p>15 you're aware that Dr. Blount's paper does not</p> <p>16 identify Johnson's baby powder in the face of</p> <p>17 the article, correct?</p> <p>18 A. I believe that's true. You'd</p> <p>19 have to go to her deposition, I believe,</p> <p>20 where she's given -- where she discusses what</p> <p>21 the source of that was, and maybe even a --</p> <p>22 there may even be a separate document,</p> <p>23 actually, not a deposition, that was -- that</p> <p>24 was in the files of Johnson & Johnson that</p> <p>25 goes along with that, but I'd have to go</p>	<p>1 information. There's information on</p> <p>2 talc powders generally, and then</p> <p>3 there's some information that's</p> <p>4 specific to certain body powders.</p> <p>5 So certainly -- would I pay</p> <p>6 attention if they identified it? Yes.</p> <p>7 But in the statement I'm making</p> <p>8 here, I'm not claiming that every one</p> <p>9 of these is relating to just the</p> <p>10 powder sold by Johnson & Johnson.</p> <p>11 This is across the available</p> <p>12 information that's public and then</p> <p>13 also the information that's available</p> <p>14 in the files of Johnson & Johnson.</p> <p>15 QUESTIONS BY MS. BRANSCOME:</p> <p>16 Q. What is your definition of</p> <p>17 asbestos?</p> <p>18 A. My definition of asbestos is</p> <p>19 exactly what the different documents describe</p> <p>20 it typically. It's a fibrous mineral,</p> <p>21 typically. It occurs in a variety of</p> <p>22 different forms. Most of the times they'll</p> <p>23 say "asbestos." Sometimes they'll say</p> <p>24 "chrysotile." Sometimes they'll say</p> <p>25 "tremolite." Sometimes they'll say</p>

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Page 254	Page 256
<p>1 "anthophyllite." Those are the three most 2 common ones I see. But those are all mineral 3 forms of asbestos. 4 So just like IARC puts those 5 all within one bin, I'm putting those all in 6 one bin because they have a similar toxicity 7 profile. 8 Q. Is it your view that each of 9 the different types of asbestos has the same 10 toxicity profile? 11 A. They all have the same ability 12 to cause cancer, but they have different 13 potencies. So they do have -- there will be 14 some differences in the dose response and the 15 potency of them, but certainly they've all 16 been linked as being carcinogens by IARC. 17 And I would agree, when you 18 look at their data, there is data and 19 evidence to indicate that. 20 Q. Which type of asbestos is the 21 most potent? 22 A. For which end point? For lung 23 cancer? I believe chrysotile is. For other 24 end points, I'd have to go look. I mean, 25 chrysotile is the sharp -- is the sharp --</p>	<p>1 A. Has to do with the fact that we 2 have a complex mixture that has multiple 3 carcinogenic substances. 4 And asbestos is important from 5 the aspect of the way that it has been 6 assessed even by regulatory bodies, the idea 7 that even very low levels of fibers pose a 8 cancer hazard and a cancer risk in 9 individuals have been shown to be 10 carcinogenic. 11 So that's what I'm saying about 12 potency of asbestos is different than potency 13 of some other carcinogens that you might look 14 at. But the importance of it is it's a 15 complex mixture, talc, body powders, a 16 complex mixture that includes constituents 17 that are known human carcinogens as well as 18 some that are -- been ranked other ways by 19 regulatory bodies. 20 Q. If Johnson's talcum powder 21 products do not contain asbestos, does that 22 change your opinion with respect to the risk 23 they pose with respect to ovarian cancer? 24 A. No, and I think that was very 25 clear if you looked at my first report. So</p>
Page 255	Page 257
<p>1 the sharded-type structure. 2 But there's data on fibrous -- 3 the fiber -- the fibrous forms of asbestos 4 rather than the -- or the amphibole forms of 5 asbestos as opposed to chrysotile, which is 6 the serpentine form. 7 Q. Do you consider yourself an 8 expert in asbestos? 9 A. Not in -- 10 MS. PARFITT: Objection. 11 THE WITNESS: Not the geology 12 of asbestos, no. 13 I have expertise in toxicology 14 as it relates to interpretation of the 15 data related to asbestos. I have 16 never give -- given testimony in a 17 case on asbestos, but it's something 18 I've studied in the past in my work as 19 a toxicologist, not as a testifying 20 expert. 21 QUESTIONS BY MS. BRANSCOME: 22 Q. What role does your analysis of 23 the possibility that there may be asbestos in 24 Johnson's talcum powder products play in your 25 risk assessment in the MDL?</p>	<p>1 even -- there's -- I don't think in any of my 2 reports I've opined that without looking at 3 the complex mixture that we wouldn't be here. 4 In other words, I have not 5 opined that if it doesn't have -- if it 6 doesn't have asbestos, it's not a risk. I 7 have not opined that, and I don't believe 8 that, because I think there is independent 9 risk for the fact that we have a complex 10 mixture of talc that has been tested and 11 shown to be carcinogenic. 12 It's my opinion, I told you -- 13 maybe it wasn't you. I may have told this 14 yesterday, I'm sorry, to Mr. Smith that I 15 believe that there is evidence to show that 16 there is a significant exposure to asbestos 17 based on the data that's been collected. 18 But certainly, you know, in 19 some -- the data has shown that in the assays 20 that have been done or the analyses that have 21 been done that you can't say that talc is 22 asbestos-free. 23 Q. Well, so -- 24 A. So -- 25 Q. -- the question I have</p>

65 (Pages 254 to 257)

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Page 258	Page 260
<p>1 specifically relates to ovarian cancer.</p> <p>2 Is it your view that through an</p> <p>3 exposure route that is relevant for ovarian</p> <p>4 cancer, that the use of Johnson's talcum</p> <p>5 products involve a substantial exposure to</p> <p>6 asbestos?</p> <p>7 A. I believe based on the use of</p> <p>8 the products that -- where the data has been</p> <p>9 collected that there would be a substantial</p> <p>10 exposure to asbestos, regardless of how</p> <p>11 you're exposed, perineal -- perineally or by</p> <p>12 inhalation.</p> <p>13 Q. What is your basis for reaching</p> <p>14 that conclusion?</p> <p>15 A. It's looking at the number of</p> <p>16 fibers that have been detected in the</p> <p>17 products, in looking at the -- the widespread</p> <p>18 nature of the presence of asbestos fiber --</p> <p>19 asbestos in the talcum powder products and</p> <p>20 the fact that even though it's at a very low</p> <p>21 level by their -- their level of detection,</p> <p>22 again, can't be said to be asbestos-free.</p> <p>23 So regardless of whether it's</p> <p>24 talc that's being applied perineally or a</p> <p>25 talc that you're inhaling while you're</p>	<p>1 asbestos above background through the</p> <p>2 perineal use of Johnson's talcum powder</p> <p>3 products?</p> <p>4 MR. MEADOWS: Objection.</p> <p>5 MS. PARFITT: Objection.</p> <p>6 THE WITNESS: I don't think</p> <p>7 that's the opinion I have formed to</p> <p>8 date, but certainly the opinion I have</p> <p>9 formed is that the data I have seen</p> <p>10 indicates that you can't separate out</p> <p>11 talc without asbestos versus talc with</p> <p>12 asbestos in the information that's</p> <p>13 been collected. Because there's --</p> <p>14 all -- the information that's been</p> <p>15 collected has shown there's no</p> <p>16 evidence that asbestos-free talc is</p> <p>17 available.</p> <p>18 If by asking that question</p> <p>19 you're trying to say that it's the</p> <p>20 asbestos alone that's causing the</p> <p>21 cancer, that is not my opinion. So</p> <p>22 that is when the dose issue would</p> <p>23 become very important for asbestos.</p> <p>24 QUESTIONS BY MS. BRANSCOME:</p> <p>25 Q. Okay.</p>
Page 259	Page 261
<p>1 applying it perineally, the fibers are still</p> <p>2 going to be present within that talc.</p> <p>3 Q. Have you or anyone done an</p> <p>4 analysis of the dose of asbestos to which</p> <p>5 someone might be exposed perineally?</p> <p>6 A. I haven't done a specific</p> <p>7 calculation, no.</p> <p>8 Q. Has anyone done that</p> <p>9 calculation?</p> <p>10 MS. PARFITT: Objection. Form.</p> <p>11 QUESTIONS BY MS. BRANSCOME:</p> <p>12 Q. That you have seen?</p> <p>13 MS. PARFITT: Objection.</p> <p>14 THE WITNESS: I'm trying to</p> <p>15 remember whether I saw that done in</p> <p>16 any of the documents related to</p> <p>17 Dr. Longo.</p> <p>18 I don't know. I'd have to go</p> <p>19 look.</p> <p>20 QUESTIONS BY MS. BRANSCOME:</p> <p>21 Q. Okay. So as you sit here</p> <p>22 today, can you give an opinion to a</p> <p>23 scientific degree of certainty, reasonable</p> <p>24 degree of scientific certainty, that an</p> <p>25 individual would be exposed to a dose of</p>	<p>1 A. So that's -- so that's a</p> <p>2 different question I have not answered.</p> <p>3 Q. And in reaching your opinion</p> <p>4 that there is no evidence that asbestos-free</p> <p>5 talc exists, you have not been provided with</p> <p>6 the reports by the defense experts, including</p> <p>7 Dr. Matthew Sanchez, analyzing Johnson's</p> <p>8 talcum powder products for the presence or</p> <p>9 absence of asbestos, correct?</p> <p>10 MS. PARFITT: Objection. Form.</p> <p>11 I think you're aware that the</p> <p>12 MDL expert reports have not yet been</p> <p>13 provided to us.</p> <p>14 MS. BRANSCOME: Yeah.</p> <p>15 MS. PARFITT: I'm just making a</p> <p>16 point.</p> <p>17 THE WITNESS: I have not seen a</p> <p>18 report by Dr. Sanchez. I assume I</p> <p>19 will, because typically after -- later</p> <p>20 in the litigation, once all experts</p> <p>21 have been deposed or revealed, I'm</p> <p>22 usually given defense expert reports</p> <p>23 and their deposition testimony. So I</p> <p>24 expect to see that; I just haven't</p> <p>25 seen it yet.</p>

Confidential - Pursuant to Protective Order

Page 262	Page 264
<p>1 QUESTIONS BY MS. BRANSCOME: 2 Q. And you haven't seen it in any 3 of the cases in which you've rendered an 4 opinion, correct, not just the MDL? 5 A. Well, none of the cases that I 6 have worked in have involved the issue of 7 looking for asbestos exposure. 8 The cases I have worked on have 9 been talking about talc exposure that may 10 include asbestos as a constituent, but it 11 wasn't focused on asbestos exposure. 12 So, no, none of the cases I 13 worked on have provided testimony in that 14 area. 15 You understand what I'm saying? 16 Q. Let me just make it clear. You 17 have not, in any of the cases in which you 18 have offered opinions with respect to the 19 contents of talc, been provided with an 20 expert report or testimony by Dr. Sanchez 21 about what he did or did not find in 22 Johnson's talcum powder products with respect 23 to asbestos? 24 MS. PARFITT: Objection. Form. 25 THE WITNESS: So I can't tell</p>	<p>1 application for any of the heavy metals. So 2 the three that I've mentioned, no, I have not 3 done that calculation. 4 Q. You would agree, based on your 5 training and experience as a toxicologist, 6 that in order for an agent -- and we can talk 7 specifically about a metal -- to present a 8 risk of cancer it needs to be bioaccessible, 9 correct? 10 A. If by bioaccessible you are not 11 limiting that definition to solubilized into 12 the blood and carried systematically, yes, I 13 would agree with that. Bioaccessible meaning 14 it has to be in a form that can somehow 15 interact with the tissue, yes, I agree with 16 that. But it could be as simple as tissue 17 contact versus needing to be solubilized. 18 Q. Okay. Is silica bioaccessible? 19 A. It depends on the form of the 20 silica. So silica particles can be 21 bioaccessible if inhaled and found on the 22 surface of the lung. That can cause injury 23 at the site of the lung. So that's an 24 accessibility to that particular tissue that 25 it contacts.</p>
Page 263	Page 265
<p>1 you that I have not. I don't recall 2 it. That's all I can say. I don't 3 recall that name. 4 QUESTIONS BY MS. BRANSCOME: 5 Q. It's certainly not something 6 you discuss in your report, correct? 7 A. No, I do not. And I don't know 8 that it's in my reliance materials. That's 9 why I'd ask you to look there, because if 10 it's in my reliance materials, then I've seen 11 it. 12 Q. Okay. 13 A. And I mean big reliance 14 material list, not my reference list. 15 Q. All right. With respect to the 16 other potential constituents of talc, have 17 you done any analysis to provide an answer as 18 to how much -- what dose of chromium, for 19 example, an individual might be exposed to 20 through the perineal use of Johnson's talcum 21 powder products over a lifetime? 22 A. No, and I have -- well, I know 23 it's a separate deposition. We discussed 24 this yesterday. No, I have not done a -- a 25 calculation of a potential dose with perineal</p>	<p>1 Q. We talked earlier -- it's 2 somewhat related to bioaccessibility, but we 3 talked about the way in which different 4 particles might move specifically through the 5 genital tract in women. 6 Do you recall that? 7 A. Yes. A general discussion. 8 Q. Yes. 9 And when you testified that 10 starch and talc might not move at the same 11 rate, do you have an opinion as to which 12 might move more quickly through the tract? 13 A. I haven't formed that opinion, 14 no. 15 Q. Okay. And do both talc and 16 starch particles remain in the body for the 17 same length of time? 18 A. I haven't done an analysis to 19 see if the data tells us what the -- what the 20 differences might be. I would expect there 21 to be differences, which is what I told you 22 earlier, because I would expect the starch to 23 be able to be solubilized, where I would not 24 necessarily expect the talc to act in that 25 same manner.</p>

67 (Pages 262 to 265)

Confidential - Pursuant to Protective Order

Page 266	Page 268
<p>1 Q. Is cornstarch capable of 2 causing an inflammatory process? 3 A. It can. It is -- but it is -- 4 it's a different level of risk for 5 inflammatory responses than is talc, just by 6 its chemical nature. 7 Q. Have you done an analysis in 8 your report that examines the differences 9 between the inflammatory response that can be 10 triggered by talc as opposed to cornstarch? 11 A. I haven't analyzed inflammatory 12 response. Instead, what I've done is done a 13 comparison of what the toxicity -- the 14 differences in the toxicity potential have 15 been described in medical literature, and I 16 cite -- I have a paragraph where I cite to 17 some sources that talk about the differences 18 in the toxicity potential or biocompatibility 19 of starch versus talc. 20 Q. Now, I had a question about 21 your supplemental report that was marked as 22 Exhibit 3 to the deposition. 23 At paragraph 67... 24 A. Okay. 25 Q. You identify here six heavy</p>	<p>1 only three heavy metals: chromium, cobalt 2 and nickel. 3 Do you see that? 4 A. Yes. 5 Q. Why did you remove three of the 6 heavy metals? 7 A. It's not so much removing. 8 Those three heavy metals that I focused on in 9 my MDL report are ones that have been talked 10 about with a similar mechanism of action as 11 far as irritation and biologic -- biologic 12 plausibility mechanism being irritation and 13 inflammation. 14 So that's why I focus on those 15 three, which may not -- which is not 16 necessarily the case for some of the others, 17 even though they're also -- have a 18 carcinogenic hazard, pose a risk. 19 Q. So in your -- as part of your 20 risk assessment that you performed in the 21 MDL, are you offering the opinion that to the 22 extent they exist in any of the Johnson 23 talcum powder products, that arsenic, lead -- 24 A. Cadmium. 25 Q. -- and cadmium play any role in</p>
Page 267	Page 269
<p>1 metals - arsenic, chromium, lead, cobalt, 2 cadmium and nickel - that in your 3 supplemental report dated August 29, 2018, 4 you say have been reported across lots of 5 talc powders. 6 Do you see that? 7 A. Are you in -- now you're in my 8 MDL report or here? 9 Q. No. 10 A. Oh, so where are you? I'm 11 sorry. 12 Q. Same report. It's the sentence 13 that begins at the bottom of page 6. 14 A. Okay. Hold on. 15 About that they have varied at 16 the levels -- 17 Q. Yes. So you identify six 18 different types of heavy metals. 19 Do you see that there? 20 A. Yes, I do. 21 Q. Okay. And the question I had 22 for you was that in your report in the MDL, 23 if you look at paragraph 36 -- 24 A. Yes. 25 Q. -- you identify -- you identify</p>	<p>1 the risk of developing ovarian cancer? 2 A. That is not an opinion that I 3 would be offering in the MDL. 4 Q. Okay. Now, you talk about 5 these heavy metals having been classified by 6 different agencies as either known probable 7 or possible human carcinogens, correct? 8 A. You're in my MDL report again? 9 Q. Oh, yes. 10 A. Okay. I'm sorry. Okay. Let 11 me get there. 12 Yeah, I do have that 13 discussion. I'm just trying to find it. 14 Q. Sure. 15 A. Okay. Yes, I'm there. 16 Q. Is it your view, based on your 17 expertise, that because a compound can cause 18 one type of cancer, it can cause all types of 19 cancer? 20 A. No, not necessarily. It 21 depends on the -- well, it depends on a 22 couple of things. It depends on what's been 23 studied. Have all types of cancer even been 24 studied. And then it also -- it also depends 25 upon, I believe, the route of exposure as</p>

68 (Pages 266 to 269)

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Page 270	Page 272
<p>1 well. So can it get to where it could cause 2 that, could it distribute there. And then in 3 addition to that, what data has been 4 collected. Is there enough data, for 5 example, to show that there's extrapolation 6 from animals to humans in the types of tumors 7 or is it -- or if we have good human data, 8 then we would focus on the types of cancers 9 that you're seeing in humans, for example. 10 Q. Okay. But you recognize even 11 where there is complete data some compounds 12 can cause one type of cancer and they are 13 incapable of causing another type, correct? 14 MS. PARFITT: Objection. Form. 15 THE WITNESS: I don't know 16 about incapable, but I would agree 17 that you certainly would see -- you 18 could potentially see different 19 observations. 20 If you're talking about animals 21 versus humans, or are you talking 22 about -- 23 QUESTIONS BY MS. BRANSCOME: 24 Q. If humans. 25 A. Based on what you had seen in</p>	<p>1 you can extrapolate with scientific basis 2 from one type of cancer cause to ovarian 3 cancer with respect to the heavy metals 4 specifically? 5 A. Well, I haven't attempted to 6 that, because I haven't attempted to define a 7 independent risk for each of those metals 8 individually. 9 The issue -- the issue I have 10 with those metals is -- there's a paragraph 11 here where I talk about pathogenesis of 12 carcinogenesis, where I talk about different 13 stages of cancer development and the fact 14 that inflammatory responses may be operating 15 at all those different stages. 16 So the issue is you have 17 potential -- you have compounds that are 18 known to produce cancer or have been shown to 19 have a potential risk of cancer. They share 20 a similar mechanism to talc, so as a result 21 of that, they factor into your risk 22 assessment as far as there being an exposure 23 to a mixture. 24 But on the issue of ovarian 25 cancer, I'm looking at the data that's been</p>
Page 271	Page 273
<p>1 the animals; is that what you're asking me? 2 Q. Yes. 3 A. Yes. So, yes, there is not 4 always a one-to-one concordance. So that's 5 why -- that's why I made the comment that 6 it's important to have some human data or 7 experience, so that you can put in context 8 the data you collected in animals. 9 I would say to you there are 10 certain kinds of tumors in animals, for 11 example, that are shown to be not relevant at 12 all to human risk assessment. Like four 13 stomach tumors in rats is an example. I've 14 dealt with that one a lot. 15 Q. What types of cancer -- type or 16 types of cancer are the basis for the 17 classification of chromium as a known human 18 carcinogen by IARC? 19 A. So I have to pull it out, but I 20 believe that there may be some GI cancers and 21 maybe some skin cancers, but I'm not sure. 22 I've got it pull it out. It's been a while 23 since I've looked at it. 24 Q. Okay. Have you done an 25 analysis to evaluate whether or not the types</p>	<p>1 collected on talc itself, which would be talc 2 with the constituents that could include the 3 metals. But certainly I'm not saying that it 4 is -- without the presence of one or the 5 other of these there would be no risk of 6 ovarian cancer. I'm not saying that either. 7 Q. So my question is, though, can 8 you point me either to scientific literature 9 directly documenting that these heavy metals 10 can cause ovarian cancer or to scientific 11 literature that enables you to extrapolate 12 from the types of cancer that they are known 13 or believed to cause to ovarian cancer? 14 A. So I -- on the issue of can I 15 point you to the data on ovarian cancer, I'd 16 have to go back. I can't answer that without 17 looking at the assessments. 18 But on the other -- second 19 question you asked me, that's the question I 20 was just trying to answer before. It's the 21 idea that regardless of where the cancer is 22 developing, the fact that these compounds 23 have the ability to stimulate similar toxic 24 responses in tissues could lead to a -- 25 setting up a situation where the -- where the</p>

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Page 274	Page 276
<p>1 tissue is primed for cancer development.</p> <p>2 Q. And do you have --</p> <p>3 A. And so that --</p> <p>4 Q. Sorry.</p> <p>5 A. And that has to do with the</p> <p>6 basic science of carcinogenesis when you look</p> <p>7 at underlying mechanisms, especially with</p> <p>8 tissue contact, direct tissue contact, with</p> <p>9 irritants or inflammatory processes.</p> <p>10 But I would -- I am not -- I</p> <p>11 have not formed the opinion, again, that with</p> <p>12 or without either one of these that I would</p> <p>13 expect ovarian cancer to be the target. I'm</p> <p>14 saying that ovarian cancer risk is increased</p> <p>15 based on exposure to talc, which includes a</p> <p>16 variety of constituents.</p> <p>17 Q. Okay. And do you cite anywhere</p> <p>18 in your report to studies documenting -- I</p> <p>19 know you said you'd need to go look at them,</p> <p>20 but I'm asking if it's in your report</p> <p>21 anywhere a discussion of any studies showing</p> <p>22 that the particular heavy metals that you</p> <p>23 cite as potential constituents of Johnson &</p> <p>24 Johnson's products have been demonstrated to</p> <p>25 increase a risk for ovarian cancer on their</p>	<p>1 So, again, that's what I'm</p> <p>2 pointing to and why I have cited the data.</p> <p>3 Q. Now, you talked about -- when</p> <p>4 we were discussing mechanism, you said that</p> <p>5 inflammation alone is not necessarily</p> <p>6 sufficient to cause cancer, correct?</p> <p>7 A. Yes, I did.</p> <p>8 Q. All right. Do you have</p> <p>9 scientific studies that show that any of the</p> <p>10 heavy metals or the fragrance constituents</p> <p>11 that you identify as potential carcinogens</p> <p>12 create -- generate phenotypic changes like</p> <p>13 you discussed were next for the formation of</p> <p>14 cancer?</p> <p>15 A. I believe that data is</p> <p>16 available on nickel. I need to go back and</p> <p>17 look at chromium and cobalt, but I do believe</p> <p>18 with nickel you'll find similar data on</p> <p>19 tissue irritation and inflammatory processes.</p> <p>20 Nickel is also a sensitizer, so</p> <p>21 it has interaction with the immune system, so</p> <p>22 I do believe that for nickel you can find</p> <p>23 some of that data.</p> <p>24 Q. Okay. But as you sit here</p> <p>25 today, can you point me into any of that</p>
Page 275	Page 277
<p>1 own?</p> <p>2 A. So, no, I haven't addressed</p> <p>3 that in my report. And again, I think that's</p> <p>4 inconsistent with the way I'm using these</p> <p>5 data. But that's fine. I mean, no, I</p> <p>6 haven't done a specific assessment of ovarian</p> <p>7 cancer risk with each of those metals</p> <p>8 individually.</p> <p>9 Q. I would ask the same questions</p> <p>10 for the different fragrance constituents that</p> <p>11 you allege in your report are potential</p> <p>12 carcinogens.</p> <p>13 Have you done any analysis, and</p> <p>14 can you point me to any scientific studies</p> <p>15 that establish that those particular</p> <p>16 compounds are capable of causing ovarian</p> <p>17 cancer?</p> <p>18 A. No, I haven't done that</p> <p>19 analysis, but, again, general principles of</p> <p>20 toxicology and cancer risk assessment, when</p> <p>21 you look at the presence of multiple --</p> <p>22 excuse me, multiple carcinogens with similar</p> <p>23 mechanisms of action, you would assume in</p> <p>24 your risk assessment that those risks could</p> <p>25 be additive.</p>	<p>1 that's discussed in your report?</p> <p>2 A. No specific discussion other</p> <p>3 than, again, all -- the IARC -- I'm citing to</p> <p>4 the IARC assessments, and the IARC</p> <p>5 assessments for each of those discuss</p> <p>6 carcinogenesis and a biologically plausible</p> <p>7 mechanism being linked to the ability of</p> <p>8 these compounds to induce oxidative stress</p> <p>9 and/or inflammatory processes.</p> <p>10 Q. Okay. In your opinion, you</p> <p>11 talk about the mixture of constituents that</p> <p>12 are involved in talc.</p> <p>13 Have you done any analysis to</p> <p>14 look at how the different constituents</p> <p>15 interact with each other?</p> <p>16 A. Well, yes, that's my issue at</p> <p>17 looking at underlying mechanism.</p> <p>18 But are you asking me -- I</p> <p>19 certainly don't have a -- the only studies</p> <p>20 that I have to rely upon on the interaction</p> <p>21 of the mixture is the actual studies on the</p> <p>22 powders themselves, where we know that the</p> <p>23 powders contain constituents other than just</p> <p>24 platy talc.</p> <p>25 Q. Okay. And do the constituents</p>

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Page 278	Page 280
<p>1 need to have the same underlying potential</p> <p>2 carcinogenic mechanism for them to have an</p> <p>3 additive effect?</p> <p>4 A. By general principles of</p> <p>5 toxicology, yes, you look at mode -- mode of</p> <p>6 action or mechanism of action before you</p> <p>7 apply that additivity principle to the cancer</p> <p>8 risk assessment.</p> <p>9 Q. And so as you sit here, you</p> <p>10 believe there have been scientific</p> <p>11 documentation that nickel might operate</p> <p>12 through the same biological mechanism as you</p> <p>13 purport talc to operate, but you're not sure</p> <p>14 about the other heavy metals or the fragrance</p> <p>15 constituents; is that correct?</p> <p>16 MS. PARFITT: Objection.</p> <p>17 THE WITNESS: For the fragrance</p> <p>18 constituents, I'd definitely have to</p> <p>19 pull because I haven't looked at that</p> <p>20 individual assessment in a while.</p> <p>21 For these three, what I do know</p> <p>22 is that they do share the ability to</p> <p>23 at least induce oxidative stress.</p> <p>24 What I can't recall for</p> <p>25 chromium and for cobalt is whether</p>	<p>1 So those two -- we'd have human data</p> <p>2 to show that.</p> <p>3 But on the issue of cobalt, it</p> <p>4 may only be -- I need to go back and</p> <p>5 look, but it may indeed just be animal</p> <p>6 data.</p> <p>7 QUESTIONS BY MS. BRANSCOME:</p> <p>8 Q. And so your basis for that</p> <p>9 would be the IARC classification?</p> <p>10 Is that where I would go to</p> <p>11 look if I wanted to look at it after this</p> <p>12 deposition?</p> <p>13 A. I'd go to the IARC reviews.</p> <p>14 I'd go to those three which I believe I have</p> <p>15 cited down here for you and given you where</p> <p>16 to go to find them.</p> <p>17 Q. Okay. You discuss in your</p> <p>18 report -- and if you'd like to reference it,</p> <p>19 it's paragraph 69 on page 47 -- the concept</p> <p>20 of genotoxic and nongenotoxic carcinogens.</p> <p>21 Do you recall that?</p> <p>22 A. Yes.</p> <p>23 Q. And as you sit here today, is</p> <p>24 it your opinion that talc is more likely a</p> <p>25 nongenotoxic carcinogen?</p>
Page 279	Page 281
<p>1 they're taking it the next step from</p> <p>2 oxidative stress to inflammatory</p> <p>3 process. I believe that they do, but</p> <p>4 I'd have to check, whereas I know</p> <p>5 nickel has been shown to lead to an</p> <p>6 inflammatory process after oxidative</p> <p>7 stress has been induced.</p> <p>8 QUESTIONS BY MS. BRANSCOME:</p> <p>9 Q. And you would agree, even more</p> <p>10 than requiring an inflammatory process, you</p> <p>11 would actually have to see that these</p> <p>12 compounds can generate phenotypic changes,</p> <p>13 correct?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 THE WITNESS: Well, we know</p> <p>16 they do because they've been shown to</p> <p>17 be carcinogenic. If you've been shown</p> <p>18 to be carcinogenic, you've done a</p> <p>19 phenotypic change in the cell from a</p> <p>20 normal cell to a cancer cell.</p> <p>21 So we know they have the</p> <p>22 capability to induce tumors, or</p> <p>23 cancer, all three of those, at least</p> <p>24 in animals if not in humans as well,</p> <p>25 because two of them are known human.</p>	<p>1 A. As the direct insult, yes. And</p> <p>2 I would like to -- I would like to point out</p> <p>3 that in the literature -- the reason I have</p> <p>4 this paragraph here is because in the</p> <p>5 literature in the past, in the area of</p> <p>6 chemicals, it's been -- toxicologists have</p> <p>7 attempted to put two bins, direct genotoxic</p> <p>8 insult versus nondirect genotoxic. It</p> <p>9 doesn't mean you can't get a genotoxic event</p> <p>10 after the initiation.</p> <p>11 So I want to make sure you</p> <p>12 understand that. I'm not saying that there</p> <p>13 is no possibility of this chemical in its --</p> <p>14 in its process of inducing cancer leading to</p> <p>15 indirect genotoxicity, but I'm talking about</p> <p>16 the direct mechanism at the site of the cell.</p> <p>17 So talc, for example, has been</p> <p>18 shown to not be genotoxic in cells. And so</p> <p>19 that's why I believe, then, when I look at</p> <p>20 the rest of the data that fits, that it fits</p> <p>21 the definition of a nongenotoxic carcinogen</p> <p>22 by its initial mechanisms to induce cancer.</p> <p>23 Q. Okay. And if talc is, in fact,</p> <p>24 a nongenotoxic carcinogen, it would suggest</p> <p>25 that there is likely a threshold dose below</p>

71 (Pages 278 to 281)

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Page 282	Page 284
<p>1 which it does not have a carcinogenic effect, 2 correct? 3 MS. PARFITT: Objection. 4 THE WITNESS: It is possible, 5 and that's the problem. In order to 6 fully assess that, you would have to 7 have the data to prove it. 8 But that's the assumption. You 9 assume with nongenotoxic carcinogens 10 that you could identify a level where 11 you wouldn't turn on that indirect 12 mechanism. So that -- yes, that is 13 true. 14 QUESTIONS BY MS. BRANSCOME: 15 Q. And you have not been able to 16 identify, nor can you point to, scientific 17 literature that identifies a threshold -- a 18 threshold dose for talc with respect to its 19 carcinogenic potential for ovarian cancer, 20 correct? 21 A. Not a specific dose, but I 22 think that's why I mentioned to you -- and 23 I -- I think that's why Canada, when you look 24 at their document, they talk about 25 discouraging routine use generally. So it's</p>	<p>1 what they've done, but is it possible 2 that they would do it? Any regulatory 3 agency, it's possible they could do 4 it, yes. 5 QUESTIONS BY MS. BRANSCOME: 6 Q. Do you have any information 7 with respect to Health Canada's 8 decision-making, other than what you have 9 read on the face of the documents? 10 A. That is all I have to look at 11 is what is provided on the website. 12 Q. Okay. And so the statement 13 that you think Health Canada was suggesting a 14 dose threshold by their statement of 15 discouraging routine use, you're basing that 16 entirely on what you read on the piece of 17 paper, correct? 18 MS. PARFITT: Objection. Form. 19 THE WITNESS: Well, that's what 20 they state. So, yes, I'm -- I am 21 telling you what I see on their 22 website. If that's what you're asking 23 me, yes, that is true. 24 QUESTIONS BY MS. BRANSCOME: 25 Q. Okay. Can you point me --</p>
Page 283	Page 285
<p>1 the issue of what -- single use of a body 2 powder or an occasional use is a different 3 risk assessment than routine use. 4 So if you want to talk about 5 thresholds that way, that's very imprecise, 6 but you could do that. You can talk about 7 whether or not there -- I do believe there's 8 a different risk profile for one or two uses 9 of talc body powder versus a risk profile of 10 somebody who uses it routinely, because I 11 think that fits that threshold definition. 12 It's the idea that you have limited 13 availability for enough particles to migrate 14 to lead to the tissue toxicity that it cannot 15 be recovered from or repair. 16 Q. You're familiar with the 17 concept of the precautionary principle, 18 correct? 19 A. Yes. 20 Q. All right. And you understand 21 that Health Canada may have made 22 recommendations with respect to product usage 23 that are purely precautionary, correct? 24 MS. PARFITT: Objection. Form. 25 THE WITNESS: I disagree that's</p>	<p>1 well, do you discuss -- have you looked at, 2 as part of your opinion specifically in the 3 MDL, the studies exploring a potential link 4 between asbestos and ovarian cancer? Just 5 asbestos. 6 A. Some of the studies, yes, but I 7 have not -- I have not done a separate risk 8 assessment just for asbestos by itself, 9 because I have not assumed that there is 10 asbestos-only exposure. 11 Does that make sense? 12 But I do cite -- for example, I 13 cite to some of the early literature on -- so 14 this -- I guess where this opinion comes in 15 is on hazard and warning. So in the warnings 16 I talk about when it was known that asbestos 17 was linked with cancer, because the warning 18 standard is not causation proven but the 19 identification of the potential. And so that 20 is in my report on warnings, but that is not 21 within my discussion of the weight of the 22 evidence for risk assessment of the talc 23 product. 24 Q. Okay. 25 A. Does that make sense?</p>

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Page 286	Page 288
<p>1 Q. Uh-huh.</p> <p>2 For example, have you rendered</p> <p>3 an opinion about what dose of asbestos</p> <p>4 exposure would be necessary to cause ovarian</p> <p>5 cancer in an individual?</p> <p>6 A. No, I have not formed that</p> <p>7 opinion at this time.</p> <p>8 Q. Okay. Do you have an opinion</p> <p>9 about the background level of asbestos to</p> <p>10 which individuals are exposed with no</p> <p>11 increased risk of any type of cancer?</p> <p>12 A. No, I do not have an opinion.</p> <p>13 I do believe others do, but I do not.</p> <p>14 Q. Okay. You may have been asked</p> <p>15 some of these questions before, but I will</p> <p>16 keep them brief.</p> <p>17 Have you ever published any</p> <p>18 articles that state that talc causes ovarian</p> <p>19 cancer?</p> <p>20 A. No, I have not.</p> <p>21 Q. Have you ever publicly</p> <p>22 expressed the opinion that talc increases the</p> <p>23 risk of ovarian cancer outside of literature?</p> <p>24 A. No. My work has been in the --</p> <p>25 in the courtroom.</p>	<p>1 not classified any of the heavy metals that</p> <p>2 you've identified in your MDL report as</p> <p>3 carcinogenic to the ovary?</p> <p>4 A. So the answer is I'd have to</p> <p>5 look. I don't recall that, but I'd have to</p> <p>6 look to confirm.</p> <p>7 Q. Okay.</p> <p>8 A. That's the answer I believe I</p> <p>9 gave a few minutes ago, yes.</p> <p>10 Q. So if I look at the IARC</p> <p>11 website, then I can confirm whether or not</p> <p>12 they have identified any of those as</p> <p>13 carcinogenic to the ovary?</p> <p>14 A. Not so much the web -- well,</p> <p>15 the website or the actual documents. I think</p> <p>16 I would actually point you to the actual</p> <p>17 monograph --</p> <p>18 Q. To the monograph.</p> <p>19 A. -- because there may be</p> <p>20 evidence in there of ovarian cancer as being</p> <p>21 seen in studies. And I'd have to go look.</p> <p>22 Q. Okay. That was not part of</p> <p>23 your consideration here, correct?</p> <p>24 A. So ovarian cancer is part of my</p> <p>25 consideration, but I didn't -- in this part</p>
Page 287	Page 289
<p>1 MS. BRANSCOME: I think we can</p> <p>2 take a break.</p> <p>3 VIDEOGRAPHER: We are going off</p> <p>4 the record at 2:57 p.m.</p> <p>5 (Off the record at 2:57 p.m.)</p> <p>6 VIDEOGRAPHER: We are back on</p> <p>7 the record at 3:13 p.m.</p> <p>8 MS. BRANSCOME: Dr. Plunkett, I</p> <p>9 have no more questions for you on</p> <p>10 behalf of Johnson & Johnson, subject</p> <p>11 to your counsel doing a direct of any</p> <p>12 kind.</p> <p>13 THE WITNESS: Sure. Thank you.</p> <p>14 EXAMINATION</p> <p>15 QUESTIONS BY MS. BOCKUS:</p> <p>16 Q. Good afternoon, Dr. Plunkett.</p> <p>17 You and I have met before. My name is Jane</p> <p>18 Bockus, and as you know, I represent Imerys</p> <p>19 in this case.</p> <p>20 A. Yes.</p> <p>21 Q. Correct?</p> <p>22 I want to go back to just touch</p> <p>23 briefly on a couple of issues that have</p> <p>24 already been addressed.</p> <p>25 Would you agree that IARC has</p>	<p>1 of my evaluation I'm trying to -- trying to</p> <p>2 describe these metals. And this is really</p> <p>3 about mechanism of biologic plausibility and</p> <p>4 the fact that these two things can go</p> <p>5 together, and then the concept of additivity</p> <p>6 is they're on hazard. The idea if you have a</p> <p>7 cancer hazard generally and you have similar</p> <p>8 mode of action, regardless of the tissue, you</p> <p>9 would be expected to have a potential</p> <p>10 additive effect when you do a risk</p> <p>11 assessment.</p> <p>12 So that's my use of that data,</p> <p>13 which is why I didn't do a separate ovarian</p> <p>14 cancer assessment for each of the each</p> <p>15 constituents but just on powder.</p> <p>16 Q. And you discuss that topic on</p> <p>17 page 47, paragraph 68, of your report,</p> <p>18 correct, the -- whether there's an additive</p> <p>19 effect?</p> <p>20 And you cite to Casarett and</p> <p>21 Doull. I don't know if I'm pronouncing those</p> <p>22 names correctly.</p> <p>23 A. I'm sorry, on what page?</p> <p>24 Q. I'm on page 47, paragraph 68.</p> <p>25 A. Okay. Sorry. I should know</p>

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Page 290	Page 292
<p>1 where it is, but...</p> <p>2 Okay. I'm there, yes. Okay.</p> <p>3 Yes, I do cite to a chapter in</p> <p>4 Casarett and Doull, yes.</p> <p>5 Q. Okay. And Casarett and Doull</p> <p>6 is a resource that you cite to for a couple</p> <p>7 of different toxicological principles that</p> <p>8 you discuss in your -- in your report,</p> <p>9 correct?</p> <p>10 A. Yes, because it's one of the</p> <p>11 most well-recognized textbooks that is used</p> <p>12 across different either universities or</p> <p>13 schools or even in regulatory agencies.</p> <p>14 I would also say I cite EPA</p> <p>15 2000 there. I'm not citing just Casarett,</p> <p>16 but I am citing Casarett as well as an EPA</p> <p>17 guidance document.</p> <p>18 Q. In Casarett and Doull, do they</p> <p>19 actually discuss talcum powder in Chapter 2,</p> <p>20 or is it more just the concept of the</p> <p>21 potential of the effects when you have two</p> <p>22 different chemicals that you're exposed to at</p> <p>23 once or three or four?</p> <p>24 A. It's the latter. It's the --</p> <p>25 because you'll notice the title is</p>	<p>1 a genetically susceptible mouse study</p> <p>2 to hurry the process along to look at,</p> <p>3 but you might not be able to do it</p> <p>4 through perineal exposure. You might</p> <p>5 have to do it through another route</p> <p>6 such as either inhalation or maybe</p> <p>7 even you could -- you could look at it</p> <p>8 through intraperitoneal injections,</p> <p>9 for example.</p> <p>10 QUESTIONS BY MS. BOCKUS:</p> <p>11 Q. Well, and what the textbook</p> <p>12 talks about is the fact that you need to</p> <p>13 study it to find out whether the effects are</p> <p>14 additive, whether the effects are something</p> <p>15 that multiply the risk, you know, so that the</p> <p>16 two together are greater than either one</p> <p>17 alone, or do the effects offset each other</p> <p>18 and reduce the risk, correct?</p> <p>19 A. That is discussed there --</p> <p>20 MS. PARFITT: Objection.</p> <p>21 THE WITNESS: -- which is why</p> <p>22 I've cited the EPA document. Because</p> <p>23 the EPA document addresses the issue</p> <p>24 of mixtures, and this is the issue of</p> <p>25 mode of action. If you have chemicals</p>
Page 291	Page 293
<p>1 "Principles of Toxicology," so it's the</p> <p>2 general chapter teaching principles for risk</p> <p>3 assessment and toxicology as used in risk</p> <p>4 assessment.</p> <p>5 Q. And whether there is an</p> <p>6 additive effect of, say, talc and nickel,</p> <p>7 that's something that an experiment could be</p> <p>8 designed to study, correct?</p> <p>9 MS. PARFITT: Objection.</p> <p>10 THE WITNESS: If you're talking</p> <p>11 generally for cancer and not worried</p> <p>12 about the issue of ovarian cancer, if</p> <p>13 you're talking about cancer, like</p> <p>14 doing an inhalation experiment to look</p> <p>15 what happens to the lung, that you</p> <p>16 could do.</p> <p>17 The problem with the animal</p> <p>18 studies and ovarian cancer due to</p> <p>19 perineal exposure is it's very</p> <p>20 difficult to understand how you design</p> <p>21 a study to expose the animals that way</p> <p>22 reliably in the way that humans are</p> <p>23 exposed.</p> <p>24 But generally you could</p> <p>25 study -- you might even be able to do</p>	<p>1 that you're looking at on the issue of</p> <p>2 additivity or no effect, you will --</p> <p>3 you look at that issue of how they're</p> <p>4 affecting the tissue and underlying</p> <p>5 mechanism.</p> <p>6 But the only way to look at the</p> <p>7 magnitude absolutely of how the risk</p> <p>8 would change is by doing an</p> <p>9 experiment. That is true.</p> <p>10 QUESTIONS BY MS. BOCKUS:</p> <p>11 Q. And to your knowledge, that</p> <p>12 experiment has never been done; is that</p> <p>13 correct?</p> <p>14 A. I can't guarantee that it's</p> <p>15 only been done for nickel and talc alone, but</p> <p>16 I would -- I would state that based on --</p> <p>17 there are studies out there that have been</p> <p>18 done where they've used the body powder that</p> <p>19 we know have metals -- a variety of things</p> <p>20 within it that are not just platy talc, but</p> <p>21 those experiments are that kind of data.</p> <p>22 But as far as gathering</p> <p>23 dose-response information or teasing out</p> <p>24 individual components, that is not available.</p> <p>25 Q. Do you agree that dose response</p>

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<p style="text-align: right;">Page 294</p> <p>1 is the fundamental principle of toxicology 2 that underpins the effects that chemicals can 3 have on living organisms? 4 A. When you're talking general 5 toxicology, yes, I think it's talked about in 6 the textbook. 7 Q. And you agree that it is the 8 dose of the chemical and the pattern of 9 exposure that determines whether a chemical 10 produces an adverse effect on an organism, 11 not simply the presence of the chemical? 12 A. For a typical dose-response 13 relationship for non -- for nongenotoxic 14 events, absolutely, I would agree that is 15 probably true. And I don't mean nongeno -- 16 noncancer events. 17 In the issue of cancer biology, 18 some of those issues don't hold all the time. 19 In other words, there are certain chemicals 20 and certain ways of looking at cancer risk 21 assessment where you can't assume where the 22 threshold is or identify what a safe dose 23 would be. But certainly I agree on the issue 24 of noncancer risk assessment generally, or 25 general end points of toxicity, that is true.</p>	<p style="text-align: right;">Page 296</p> <p>1 A. That is true with the exception 2 of Parmley and Woodruff, which addresses this 3 issue of -- 4 MS. PARFITT: Objection. 5 THE WITNESS: Talks about the 6 issue of exposure from the outside to 7 the inside. 8 But the data that is collected 9 with the different studies they have 10 deposited at some point -- at some 11 position within the vagina, that is 12 true. 13 QUESTIONS BY MS. BOCKUS: 14 Q. And that is not how talc is 15 deposited in women who use it regularly in 16 their daily routine, correct? 17 MS. PARFITT: Objection. 18 Misstates the evidence. 19 THE WITNESS: So I would say 20 that depends on what women are doing. 21 Perineal application, for example, 22 application on the underwear, can lead 23 to contact of the vaginal opening 24 depending on the woman. 25 For example, a woman who has</p>
<p style="text-align: right;">Page 295</p> <p>1 Q. And again, do you agree that in 2 general toxicology the effects that might be 3 reported at high doses will not occur at 4 lower doses if the concentration at the site 5 of action falls below the threshold for 6 toxicity? 7 A. Yes, that could -- that could 8 be possible, yes. 9 Q. And do you agree that 10 evidence-based toxicology and epidemiology 11 dictates that the dose of the chemical is the 12 critical factor when examining the risk posed 13 by a chemical, not just its presence even in 14 the human body? 15 A. I would say that's generally 16 true, yes, which is why I have attempted to 17 look at the dose-response relationship as 18 well as the prevalence of the contact. 19 Q. And with regard to the human 20 studies that you cite, would you agree that 21 none of the studies that you cite in your 22 report that have to do with migration of 23 particles within the genital tract of the 24 female involve applications to the perineum 25 or outside of the genital tract?</p>	<p style="text-align: right;">Page 297</p> <p>1 a -- had many children has a tract 2 that is stretched. There, indeed, you 3 can have more direct contact than you 4 can with a very tight -- so I would 5 say it depends on the woman and it 6 depends on the situation. 7 But I do think it's generally 8 accepted, based on my review of the 9 literature, that there is the 10 opportunity for exposure internally 11 from perineal application. 12 QUESTIONS BY MS. BOCKUS: 13 Q. And if I understand what you 14 testified to earlier today and yesterday, you 15 don't have any data that would advise on -- 16 out of the talc that is deposited in the 17 underwear, what percentage of it makes it 18 into the reproductive tract? 19 A. That's the data that's missing, 20 that is true. And unfortunately, no one has 21 done a study. It would be -- if there was a 22 way to do that, it would be interesting to do 23 that. I just don't see how you design that 24 study, especially knowing the hazard of talc 25 at this point. I think that would be a</p>

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<p style="text-align: right;">Page 298</p> <p>1 difficult study to get approval for. 2 Q. And do you have an opinion as 3 to whether it is even correct that each day 4 that a woman uses talc in her underwear, that 5 some of the talc makes its way to the ovary? 6 MS. PARFITT: Objection. Form. 7 THE WITNESS: Have I -- can I 8 quantify that? 9 No, I haven't quantified it. I 10 think I got asked that earlier. I 11 can't quantify the amount that gets 12 there. Or, I'm sorry, I may have 13 misheard the start of your question. 14 I apologize. 15 QUESTIONS BY MS. BOCKUS: 16 Q. Yeah, I'm really asking: Do 17 you have an opinion as to whether it happens 18 every single time a woman applies talc to her 19 perineal area? Does some of that talc make 20 it to her ovary? 21 MR. MEADOWS: Objection. 22 MS. PARFITT: Objection. 23 THE WITNESS: I don't think I 24 stated it quite that way, but 25 certainly I think the opportunity is</p>	<p style="text-align: right;">Page 300</p> <p>1 migration occurs every day, once a week, once 2 a month? 3 MS. PARFITT: Objection. Form. 4 THE WITNESS: I haven't 5 formulated my point -- my opinion 6 quite that way; however, I do believe 7 that it is something that is going to 8 happen routinely with exposure. I do 9 believe that migration is something 10 that is going on routinely with 11 application. 12 So with applications, I do 13 believe that that is, but I can't tell 14 you that this amount has migrated on 15 this particular day with this 16 particular application, no. That -- 17 the data that we have collected is not 18 there to allow us to do that. 19 QUESTIONS BY MS. BOCKUS: 20 Q. How do you define the word 21 "routinely" as you're using it in that 22 answer? 23 A. So that would be the idea of 24 repeated exposures, you know, within a week, 25 within a month, within a year. So not --</p>
<p style="text-align: right;">Page 299</p> <p>1 there with every application. And of 2 course it would depend upon the amount 3 of time that the contact may be in 4 place. But the opportunity is there. 5 So, for example, if you applied 6 it to your underwear and 30 minutes 7 later you go to the bathroom, it's 8 very possible that you will have wiped 9 away, and so that that application may 10 have taken an opportunity away. But I 11 do believe that the opportunity is 12 there based on the literature I have 13 seen. 14 And so I haven't formed the 15 opinion, though, that it's absolutely 16 every time. My opinion, I think, is 17 based on the fact that I believe that 18 there is data to indicate that 19 exposure occurs, and that with 20 routine, continual habit, sort of a 21 habit exposure, that indeed that there 22 was some migration that occurs. 23 QUESTIONS BY MS. BOCKUS: 24 Q. And is it fair to say that you 25 don't have an opinion as to whether that</p>	<p style="text-align: right;">Page 301</p> <p>1 routine to me would not be -- would not be 2 applying it once a month one month, waiting 3 six months, doing it again, and then not 4 doing it until the next year. 5 Again, it's the idea -- some 6 people may -- routine may be during the hot 7 season of the year, they're routinely getting 8 daily exposures when it's warm, and during 9 the cold weather not applying. But then the 10 next year doing -- that's a routine for them 11 and their habits based on their pattern of 12 exposure. 13 Again, we know that talc, when 14 it -- when it migrates and gets into the 15 body, we have data to show that it is -- it 16 is able to persist in the body. The fact 17 that you may have not been exposed for three 18 months because it was cold doesn't mean that 19 you -- that that changes the fact that you're 20 still at risk with additional exposures the 21 next -- the next time that that habit 22 becomes -- comes into place. 23 So I think there's multiple 24 exposure patterns that are possible, but when 25 I use routine, it's something that people are</p>

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Page 302	Page 304
<p>1 doing throughout their -- a period of their</p> <p>2 life. And so it would be something that</p> <p>3 happens either on a weekly basis for a good</p> <p>4 part of the year. I haven't defined it with</p> <p>5 a particular number, though, no.</p> <p>6 Q. And my question had to do with</p> <p>7 out of the number of times a given woman --</p> <p>8 or an average woman uses talc, what</p> <p>9 percentage of the time does talc make its way</p> <p>10 into her reproductive tract?</p> <p>11 A. So I don't think that</p> <p>12 anybody -- anybody can point to a piece of</p> <p>13 data that tells you that, but, again, it's</p> <p>14 based upon the anatomy, I would expect there</p> <p>15 to be the potential each time it's applied.</p> <p>16 And on your question on</p> <p>17 routine, when I'm talking routine, I'm</p> <p>18 looking at not just frequency but also</p> <p>19 duration. So when I'm talking about dose,</p> <p>20 it's the fact that they do it on a repeated</p> <p>21 basis for a number of -- a period of years as</p> <p>22 well.</p> <p>23 That's what the data shows in</p> <p>24 the human studies. It's not something,</p> <p>25 again, that may have been done routinely for</p>	<p>1 opinion on a set number, no. I can't --</p> <p>2 can't point you a specific number.</p> <p>3 I'm not doing case-specific, so</p> <p>4 I've not looked at any of those pieces of</p> <p>5 information for any given plaintiff.</p> <p>6 Q. And I'm just trying to get the</p> <p>7 threshold.</p> <p>8 A. Uh-huh.</p> <p>9 Q. As I understand it, that is</p> <p>10 part of a toxicological evaluation, is the</p> <p>11 threshold below which there's not an issue.</p> <p>12 So I think you've said you</p> <p>13 don't know if it's less than a year, but you</p> <p>14 think it's more likely than not that it's</p> <p>15 greater than one month.</p> <p>16 MR. MEADOWS: Objection.</p> <p>17 QUESTIONS BY MS. BOCKUS:</p> <p>18 Q. Is that fair?</p> <p>19 A. No, that's not exactly what I'm</p> <p>20 saying. I'm saying we don't know the</p> <p>21 threshold. So as a result, I'm not of the</p> <p>22 opinion that it absolutely can't -- it only</p> <p>23 has to be this long.</p> <p>24 What I'm saying to you is per</p> <p>25 general principles of toxicology and based on</p>
Page 303	Page 305
<p>1 one year, but it does appear to be something</p> <p>2 that's done more -- longer term than that.</p> <p>3 But we can't give a number. We</p> <p>4 have no threshold. We don't know exactly</p> <p>5 what that minimum number is.</p> <p>6 Q. Do you think that the minimum</p> <p>7 number is greater than a year?</p> <p>8 MS. PARFITT: Objection. Form.</p> <p>9 THE WITNESS: I haven't formed</p> <p>10 that opinion, no.</p> <p>11 QUESTIONS BY MS. BOCKUS:</p> <p>12 Q. Do you think it's greater than</p> <p>13 a month?</p> <p>14 MR. MEADOWS: Objection.</p> <p>15 THE WITNESS: Greater than a</p> <p>16 month?</p> <p>17 QUESTIONS BY MS. BOCKUS:</p> <p>18 Q. Yes.</p> <p>19 A. One month in their life?</p> <p>20 Q. One month in their life, where</p> <p>21 they're using it every day for a month.</p> <p>22 A. So I haven't formed that</p> <p>23 opinion at this point in time, but I'd say</p> <p>24 it's more likely to occur when you do it more</p> <p>25 than a month. But I haven't formed an</p>	<p>1 the human data that we have, it indicates</p> <p>2 that it's more frequent than just one month,</p> <p>3 but I can't tell you that it's absolutely not</p> <p>4 possible.</p> <p>5 That's where -- I do think when</p> <p>6 you're talking about those kinds of patterns,</p> <p>7 that's a case-specific issue for individuals,</p> <p>8 because I think that would have to be</p> <p>9 considered for each individual. But</p> <p>10 certainly as a toxicologist, I'm using the</p> <p>11 words "routine," "repeated," "longer</p> <p>12 duration," "chronic exposure." And when I</p> <p>13 defined "chronic" earlier, I talked about</p> <p>14 years of exposure versus just one month.</p> <p>15 That would be consistent with</p> <p>16 what I have said, yes, but I'm not -- I -- I</p> <p>17 certainly don't want to rule out that there</p> <p>18 couldn't be somebody out there that could</p> <p>19 show something different, because it may very</p> <p>20 well be that there are people that you can</p> <p>21 identify with the presence of talc in their</p> <p>22 ovaries and all of their other case-specific</p> <p>23 things that could -- could make that pattern</p> <p>24 a -- make someone be able to draw a</p> <p>25 case-specific, reliable conclusion.</p>

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Page 306	Page 308
<p>1 But that's not my role. I</p> <p>2 don't do case-specific.</p> <p>3 Q. And I am simply trying to get</p> <p>4 the parameters of your opinions with regard</p> <p>5 to the amount of talc use one would need to</p> <p>6 have before you would feel comfortable --</p> <p>7 well, that in your opinion would be</p> <p>8 sufficient to create a toxic environment.</p> <p>9 MR. MEADOWS: Objection.</p> <p>10 THE WITNESS: Well, that's a</p> <p>11 different question. So toxic</p> <p>12 environment could be with a much</p> <p>13 shorter time exposure, okay?</p> <p>14 QUESTIONS BY MS. BOCKUS:</p> <p>15 Q. Right.</p> <p>16 A. So but if you're talking</p> <p>17 about -- the opinion that I have formed has</p> <p>18 to do with an increased risk of ovarian</p> <p>19 cancer. So with that opinion, that's the</p> <p>20 description, I believe, I was giving this</p> <p>21 morning. It's the idea that the data that</p> <p>22 I've seen indicates that my opinion that</p> <p>23 perineal use of talc body powder products</p> <p>24 increases your risk for ovarian cancer above</p> <p>25 that background level that you know exists.</p>	<p>1 QUESTIONS BY MS. BOCKUS:</p> <p>2 Q. Okay. An ingredient supplier.</p> <p>3 And you agree that Imerys does</p> <p>4 not sell any products to the general public,</p> <p>5 correct?</p> <p>6 MR. MEADOWS: Objection.</p> <p>7 THE WITNESS: I don't know</p> <p>8 that's definitely true, but I'm not</p> <p>9 aware that they do.</p> <p>10 QUESTIONS BY MS. BOCKUS:</p> <p>11 Q. And what Imerys supplies to</p> <p>12 Johnson & Johnson is not a finished cosmetic</p> <p>13 that is ready to be sold on the market,</p> <p>14 correct?</p> <p>15 MR. MEADOWS: Objection.</p> <p>16 MS. PARFITT: Objection.</p> <p>17 THE WITNESS: I don't know that</p> <p>18 I can answer that except in the</p> <p>19 context of Johnson & Johnson's baby</p> <p>20 powder, SHOWER TO SHOWER® and Shimmer,</p> <p>21 it's my understanding that Johnson &</p> <p>22 Johnson mixes -- has some fragrance</p> <p>23 added to the talc.</p> <p>24 I don't believe Imerys does</p> <p>25 that, but I don't know for sure.</p>
Page 307	Page 309
<p>1 That opinion is based on data</p> <p>2 that is -- is -- the supporting data would</p> <p>3 indicate that it has to be a habit, routine,</p> <p>4 a chronic exposure. And so as a</p> <p>5 toxicologist, I've tried to put that in</p> <p>6 context.</p> <p>7 I don't know what else to tell</p> <p>8 you. That's the opinions I have formed to</p> <p>9 date.</p> <p>10 Q. A chronic -- a habit, routine,</p> <p>11 a chronic exposure for years?</p> <p>12 A. Well, chronic --</p> <p>13 MR. MEADOWS: Objection.</p> <p>14 THE WITNESS: -- is defined as</p> <p>15 years, typically, by a toxicologist,</p> <p>16 and so that's what I -- that's what I</p> <p>17 told you.</p> <p>18 QUESTIONS BY MS. BOCKUS:</p> <p>19 Q. Shifting to your regulatory</p> <p>20 opinions, you would agree that Imerys is a</p> <p>21 raw material supplier to J&J; is that</p> <p>22 correct?</p> <p>23 MR. MEADOWS: Objection.</p> <p>24 THE WITNESS: I would call them</p> <p>25 an ingredient supplier, yes.</p>	<p>1 So based on what I know -- I'm</p> <p>2 telling you what I know, and I would</p> <p>3 call them, again, an ingredient</p> <p>4 supplier, and I would call Johnson &</p> <p>5 Johnson a cosmetic manufacturer.</p> <p>6 Does that answer the question?</p> <p>7 QUESTIONS BY MS. BOCKUS:</p> <p>8 Q. It does.</p> <p>9 Would you agree that the</p> <p>10 minerals that you have identified in your</p> <p>11 report, that the documents that you have</p> <p>12 seen, would classify their -- to the extent</p> <p>13 that they are ever in the powder, that</p> <p>14 they're trace ingredients?</p> <p>15 MS. PARFITT: Objection.</p> <p>16 MR. MEADOWS: Objection.</p> <p>17 THE WITNESS: So which</p> <p>18 ingredients are you referring to?</p> <p>19 So some of the metals, no, are</p> <p>20 not trace ingredients.</p> <p>21 Are you talking about the --</p> <p>22 are you talking about the -- like the</p> <p>23 presence of tremolite or the presence</p> <p>24 of chrysotile --</p> <p>25</p>

78 (Pages 306 to 309)

Confidential - Pursuant to Protective Order

Page 310	Page 312
<p>1 QUESTIONS BY MS. BOCKUS: 2 Q. No. No, I'm sorry. I'm 3 talking about the three metals that you 4 identify in your report. Those are trace 5 elements that are -- that are sometimes 6 detected in the studies of the -- of the 7 talc. 8 MR. MEADOWS: Objection. 9 THE WITNESS: It's not how I 10 would say it. I would say they're 11 heavy metal components that are 12 naturally occurring within the product 13 that are sometimes -- sometimes 14 detectable at levels that are reported 15 as trace based on the detection limit 16 within the analysis, but at other 17 times they're not listed as trace. 18 They're actually listed with a 19 specific amount. 20 So that's what -- how I would 21 define what I call trace. Usually 22 that's how it will be reported in the 23 lab, trace, which means below the 24 limit of quantification, but it's 25 there. You're detecting it.</p>	<p>1 QUESTIONS BY MS. BOCKUS: 2 Q. Have you seen any studies where 3 women's blood has reflected the presence of 4 nickel or cobalt or chromium? 5 MR. MEADOWS: Objection. 6 QUESTIONS BY MS. BOCKUS: 7 Q. Who are parts of these 8 studies -- these ovarian cancer studies? 9 MR. MEADOWS: Objection. 10 THE WITNESS: The 11 epidemiological literature you're 12 asking me? 13 QUESTIONS BY MS. BOCKUS: 14 Q. Yes, ma'am. 15 A. It's possible in the Nurses' 16 Health Study that we can go to that, because 17 I know they do collect some heavy metal 18 levels. I've done that for other clients on 19 other issues. 20 Most of the others, I doubt 21 that we have heavy metal levels in blood. 22 But certainly there are levels of heavy metal 23 in blood, especially things like lead, for 24 example, that we have very limited capacity 25 to eliminate.</p>
Page 311	Page 313
<p>1 I would agree that -- that 2 there are other descriptions of heavy 3 metals in the heavy metal literature 4 that talk about trace amounts being 5 found in -- naturally occurring in 6 food, for example, and I agree that 7 that does occur. But in the case of 8 this product, we actually have 9 often -- we actually have a -- a limit 10 that is set for acceptability in the 11 specification. 12 And so I would think it's more 13 proper to call it a level of the heavy 14 metal that is allowable by the purity 15 specifications set by the product. 16 And sometimes those levels may be 17 above, and most of the times those 18 levels are below, which is why it's 19 cleared. Because I've seen some 20 analyses where different products may 21 have been, I guess, turned away or 22 considered not acceptable based on the 23 analysis of certain types of minerals 24 or metals. 25</p>	<p>1 So whether or not you carry 2 around a significant body burden of a heavy 3 metal in your blood is somewhat driven by the 4 exposure pattern you get. It's something 5 that's commonly -- or can you excrete it 6 quickly or not. So... 7 Q. And are you familiar with any 8 studies that have suggested that the use of 9 body powders leads to a heavy burden of 10 nickel, chromium or cobalt in the blood? 11 A. So I have not seen such 12 analysis done, no, I have not. 13 Q. In paragraph 67 of your report, 14 which is on page 46 -- I'm sorry, on -- oh, 15 I'm sorry. Paragraph 64, I apologize. 16 A. No. No, that's fine. 17 Q. It's on page 44. 18 You cite to two abstracts -- 19 A. Yes. 20 Q. -- one by Fletcher and one by 21 Fletcher and Saed. 22 Do you consider these abstracts 23 to be reliable sources of data? 24 A. They're not as reliable at all 25 as a peer-reviewed article. So there's a</p>

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<p style="text-align: right;">Page 314</p> <p>1 difference in the weight you give an 2 abstract, absolutely. 3 However, knowing the papers 4 that Dr. Saed has actually published in the 5 peer-reviewed literature, I have -- I have 6 mentioned them in here because I do believe 7 that they are -- they are pieces of 8 information that are highly relevant to some 9 of the issues raised in other cellular 10 studies, and so that's why they're here. But 11 certainly I do not give them the same weight 12 as in my assessment of overall risk. 13 And I would say that I had the 14 same opinions on risk before I had these 15 studies. Because in my original reports, 16 obviously, I have gone further than risk and 17 talked about cause, and I didn't have the 18 Fletcher studies. 19 The Fletcher studies are more 20 on the issue of biologic plausibility and 21 mechanism versus being important 22 underpinnings, for example, for a hazard 23 assessment. 24 Q. Is there any way that someone 25 reading your report could tell that you</p>	<p style="text-align: right;">Page 316</p> <p>1 A. I attempted to do that. I 2 can't tell that you there isn't something in 3 here I've missed. But, yes, I read this 4 report six or seven times before I finalized 5 it, trying to make sure that the language I 6 was using was an accurate reflection of the 7 opinion I'm expressing. 8 But it's possible, if you want 9 to point to something that you want to ask me 10 about, I can tell you whether or not that was 11 something that I would change. 12 Q. So on page 77, paragraph 118 in 13 the middle of it, you say, "Based on the 14 knowledge available by the 1950s, talc body 15 powders manufactured and sold by Imerys and 16 Johnson & Johnson." 17 And that's the question that I 18 have for you. 19 A. I see what you're saying. 20 Q. Was Imerys selling anything to 21 Johnson & Johnson in the 1950s? 22 MR. MEADOWS: Objection. 23 THE WITNESS: I'm thinking. 24 It's possible they did not. That may 25 be true.</p>
<p style="text-align: right;">Page 315</p> <p>1 attribute less weight to the abstracts by 2 Saed and Fletcher just by reading your 3 report? 4 MR. MEADOWS: Objection. 5 THE WITNESS: I don't know if 6 they could or not. Hopefully they 7 would based upon where they appear in 8 the report. They're not cited a lot 9 of other places, but they certainly 10 are cited. 11 So that's why I'm here today, 12 though. You're asking me these 13 questions; I'm telling you. That's 14 how I look at these studies. That's 15 all I can say. 16 I haven't -- I haven't, 17 certainly, as I've told you, given 18 things numerical weight throughout my 19 report. 20 QUESTIONS BY MS. BOCKUS: 21 Q. Looking at paragraph 118... 22 Well, when you were preparing 23 your report, were you careful with the 24 language that you used in it to be precise 25 and accurate?</p>	<p style="text-align: right;">Page 317</p> <p>1 QUESTIONS BY MS. BOCKUS: 2 Q. Well, and actually -- 3 A. You know what? When I wrote 4 this sentence, I assumed that they did, but 5 if that is not true, then certainly this 6 sentence should be just Johnson & Johnson. 7 Q. Well, earlier in your report, 8 in a footnote you indicate that Imerys began 9 supplying talc to Johnson & Johnson in 1989 10 or the late 1980s. 11 Do you remember making that 12 notation? 13 A. So let me look. So if that's 14 an inconsistency, then that should change. 15 Let me look. 16 Q. And that's all I want to know, 17 if it's an inconsistency, should it change. 18 A. If it is an inconsistency -- 19 certainly if Imerys was not selling talc to 20 Johnson & Johnson in 19 -- the 1950s, then -- 21 then certainly Johnson & Johnson's products 22 would not -- would not be affected by Imerys' 23 activity. 24 However, if Imerys is selling 25 talc to anyone that makes a consumer product</p>

Confidential - Pursuant to Protective Order

Page 318	Page 320
<p>1 in the 1950s, then -- or a precursor company</p> <p>2 to Imerys is making talc that's selling for</p> <p>3 body powder to somebody other than Johnson &</p> <p>4 Johnson, then that opinion would still hold.</p> <p>5 So -- but I certainly agree, I</p> <p>6 think I -- you're right, I think I have a</p> <p>7 statement about the link between the two in</p> <p>8 '89. So in that case, then certainly the --</p> <p>9 the link here would be related to Johnson &</p> <p>10 Johnson's products.</p> <p>11 Q. Okay. Yeah.</p> <p>12 A. Whether or not -- if they</p> <p>13 weren't sourced from Imerys, then that's a</p> <p>14 separate duty on a product, not this product.</p> <p>15 Q. If you look on the bottom of</p> <p>16 page 7, I think you'll see the footnote I was</p> <p>17 referencing.</p> <p>18 And with regard to your last</p> <p>19 answer, you don't have any information as to</p> <p>20 whether Imerys existed and, if it did,</p> <p>21 what -- who its customers were in 1950s,</p> <p>22 correct?</p> <p>23 A. I don't believe I do, no.</p> <p>24 MS. BOCKUS: I think that's all</p> <p>25 that I have. Thank you.</p>	<p>1 complete assessment the way I did, then I</p> <p>2 would agree that other people could come to a</p> <p>3 different conclusion, absolutely.</p> <p>4 So I think it depends what you</p> <p>5 mean by "reasonable scientist." But I would</p> <p>6 agree that individuals can look at the same</p> <p>7 body of data and, based on their judgment and</p> <p>8 experience, based on looking at that same</p> <p>9 body of data, could come to a different</p> <p>10 conclusion, yes. That's true.</p> <p>11 Q. You've been involved in this</p> <p>12 talc litigation for at least a couple of</p> <p>13 years, right?</p> <p>14 A. Yes.</p> <p>15 Q. And you know that various</p> <p>16 defendants have offered experts who disagree</p> <p>17 with your conclusions, right?</p> <p>18 A. Some of my conclusions, yes. I</p> <p>19 don't know that there is somebody that's in</p> <p>20 the litigation that does exactly what I do</p> <p>21 across all the opinions I've expressed, but,</p> <p>22 yes, certain parts of my opinions there are</p> <p>23 other experts I'm aware of, yes.</p> <p>24 Q. Well, they -- you're aware that</p> <p>25 there are defense experts who disagree with</p>
Page 319	Page 321
<p>1 MR. LOCKE: I've got a few</p> <p>2 questions.</p> <p>3 EXAMINATION</p> <p>4 QUESTIONS BY MR. LOCKE:</p> <p>5 Q. Doctor, my name's Tom Locke. I</p> <p>6 represent the Personal Care Products Council.</p> <p>7 We met a couple of times before, I think.</p> <p>8 A. I apologize, I don't recall</p> <p>9 your name at least. The face looked</p> <p>10 familiar, though. I apologize.</p> <p>11 Q. I try to maintain a low</p> <p>12 profile.</p> <p>13 I have relatively few</p> <p>14 questions. I wanted to ask you overall about</p> <p>15 your opinion.</p> <p>16 Would you agree that reasonable</p> <p>17 scientists can disagree with your opinion</p> <p>18 that talc increases the risk of ovarian</p> <p>19 cancer?</p> <p>20 A. I'd say I wouldn't say it quite</p> <p>21 that way. I'd say that I agree that</p> <p>22 scientists can disagree on conclusions they</p> <p>23 draw, depending on the -- depending on the</p> <p>24 way that they have assessed.</p> <p>25 So certainly based on a</p>	<p>1 your opinion that talc increases the risk of</p> <p>2 ovarian cancer; is that correct?</p> <p>3 A. Yes, I -- I am aware of that</p> <p>4 fact.</p> <p>5 Q. And in your review of the</p> <p>6 records that go back or the scientific</p> <p>7 materials that go back 35 years or more,</p> <p>8 you've seen that there's disagreement</p> <p>9 regarding that issue; is that correct?</p> <p>10 A. So what documents are you</p> <p>11 referring to? Are you asking me about a</p> <p>12 specific -- just the published medical</p> <p>13 literature? Are you asking about documents</p> <p>14 like internal company documents, reviews by</p> <p>15 others? What are you asking me about?</p> <p>16 Q. Well, let's focus on the</p> <p>17 published medical literature.</p> <p>18 There are scientists who have</p> <p>19 disagreed with your opinion; is that correct?</p> <p>20 MS. PARFITT: Objection.</p> <p>21 THE WITNESS: I'm not aware of</p> <p>22 a paper in the published medical</p> <p>23 literature that has done the exact</p> <p>24 assessment I have done.</p> <p>25 So I am aware of the fact,</p>

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Page 322	Page 324
<p>1 however, that there are individual 2 papers by scientists that, for 3 example, have concluded that there is 4 no association between exposure to 5 talc perineally and ovarian cancer, 6 yes. Individual papers, I am aware of 7 that, but that's different than what I 8 have done. 9 QUESTIONS BY MR. LOCKE: 10 Q. Let me just ask you about what 11 you were requested to do on behalf of 12 plaintiff's counsel. 13 Plaintiff's counsel asked you 14 to provide opinions related to the human 15 health hazards posed by exposure to talcum 16 powder products and how those hazards relate 17 to the regulatory requirements for marketing 18 cosmetic ingredients and cosmetic products in 19 the United States; is that correct? 20 MR. MEADOWS: Objection. 21 THE WITNESS: I didn't write 22 that, but that sounds like an accurate 23 reflection of what -- what we -- what 24 I have done at least in parts of my 25 report, yes.</p>	<p>1 what I've been doing in the litigation. 2 Q. Okay. As to that second 3 bucket, the US regulatory requirements for 4 marketing cosmetic ingredients and products, 5 that's not relevant to the scientific 6 question whether talc may cause ovarian 7 cancer; am I right? 8 A. No. I disagree with that based 9 on the fact that a company that markets a 10 cosmetic product is required to do a safety 11 assessment. And if in that safety assessment 12 issues relate to cancer or ovarian cancer and 13 the use of talc, then those two things are 14 related. 15 But I would agree that -- that 16 doing a risk assessment like I've done is a 17 separate issue from doing a safety assessment 18 for a product, because there's actually even 19 a lesser standard for an issue of looking at 20 a safety assessment for a product versus 21 actually forming the opinion that there is an 22 increased risk of cancer with exposure to 23 talc. 24 Q. Now, did IARC in 2006, did it 25 look at the US regulatory process in</p>
Page 323	Page 325
<p>1 QUESTIONS BY MR. LOCKE: 2 Q. Well, if you look at your 3 report, I think you go to part where you were 4 asked to provide -- and I just pulled it from 5 what you said. 6 A. So I did write it, I apologize. 7 It didn't sound like me. 8 Q. It started with "to provide 9 opinions related to the human health hazards" 10 and so forth, so I just wanted to make sure 11 we're clear on that. 12 A. Sure. 13 Q. So does that sound right in 14 terms of what you were asked to do? 15 A. I said I -- certainly those are 16 the kinds of things that I was definitely 17 asked to do. I was asked to do two basic -- 18 two basic things, which was having to do with 19 toxicology and risk assessment, and then a 20 separate issue related to regulatory 21 concerns. 22 So, yes, those are the two 23 basic, I guess, buckets of information and 24 documents that I reviewed and opinions I've 25 expressed, and I think that's consistent with</p>	<p>1 considering whether talc may cause ovarian 2 cancer? 3 MR. MEADOWS: Objection. 4 THE WITNESS: I don't think I 5 understand what you mean. It's not a 6 US regulatory process, no, if that's 7 what you're asking me. 8 They have a -- they have a 9 discussion of what the products are, 10 which is part of the way they're sold. 11 But I don't think they're discussing 12 the duty of a company under the 13 regulatory process, no, that's a 14 separate issue. 15 QUESTIONS BY MR. LOCKE: 16 Q. So their analysis of whether 17 talc may cause ovarian cancer, that's 18 different than the analysis of whether a 19 company may have a duty, whatever that duty 20 may be? 21 MR. MEADOWS: Objection. 22 THE WITNESS: It's a different 23 process, absolutely. IARC is a 24 separate, independent body that does 25 an assessment looking at the issue of</p>

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Page 326	Page 328
<p>1 cancer hazard and looking at whether 2 or not there is sufficient evidence to 3 categorize that hazard, whereas a duty 4 of a company under the regulatory 5 situation is broader than just cancer 6 hazard; it's a whole different thing. 7 It's what you do internally before you 8 market a product. Totally different. 9 And so certainly when I -- 10 that's why I have separate sections in 11 my report, and that's why I even 12 have -- I've had discussions about the 13 difference between the regulatory 14 standard for warning versus the 15 assessment of risk that may be 16 required in order to start to produce 17 a -- identify a association or an 18 increased risk or even if you did a 19 causation analysis. Totally different 20 type of exercise. 21 QUESTIONS BY MR. LOCKE: 22 Q. Do you first, in that exercise, 23 look at the scientific issue of whether talc 24 may cause ovarian cancer? 25 A. Are you asking me in either of</p>	<p>1 this is a different assessment and 2 different standard. It's a much lower 3 standard on cosmetics for what needs 4 to be done as far as warning. 5 Now, when a company comes and 6 initiates a safety assessment on their 7 product, before they even think about 8 what am I going to warn, they should 9 be doing a comprehensive assessment of 10 safety based on what's available 11 publicly, knowing what others have 12 reported and then what data they've 13 collected. 14 If they don't have data at all 15 on the safety of the product, then the 16 product has to say that. We don't 17 know. We do not know if this product 18 is safe. And that's one of the things 19 that is allowed under FDA -- under FDA 20 regulations as well. 21 But essentially some -- some 22 assessment must be done to understand 23 from the perspective of the company 24 that this product is safe for 25 consumers to use as -- under the</p>
Page 327	Page 329
<p>1 these exercises? 2 Q. Well, let's say when you're 3 getting to -- you mentioned the duty to warn. 4 So if you're looking at the duty to warn, do 5 you first have to look at does talc cause 6 ovarian cancer? 7 MR. MEADOWS: Objection. 8 THE WITNESS: That's not the 9 question you asked. No. I would 10 argue, based on the regulations, if 11 you look at the standard, the question 12 is, is there evidence to indicate that 13 there is a chance, there is a 14 potential -- not that it does, but is 15 there a potential for that type of 16 hazard to be posed to consumers who 17 use the product. 18 It's a possibility versus being 19 a -- I'm taking it beyond possibility 20 when I'm doing my assessment for 21 increased risk. And I talked about 22 that this morning, and I can't 23 remember her last name. The 24 Johnson -- I apologize. But I -- with 25 Johnson & Johnson. I talked about</p>	<p>1 directions of use. 2 So in the case of this, it 3 would be a body powder being used on 4 the body surface but also perineally 5 because -- because that was an 6 exposure pattern that was understood. 7 QUESTIONS BY MR. LOCKE: 8 Q. Okay. You described two 9 different buckets. They're independent 10 assessments; is that correct? 11 MR. MEADOWS: Objection. 12 THE WITNESS: Initially that's 13 where I started, and now I'm talking 14 two different duties. There's a duty 15 to warn, but there's first a duty to 16 collect information before you market 17 it. It's your premarket safety 18 assessment. 19 QUESTIONS BY MR. LOCKE: 20 Q. Okay. I'm not actually talking 21 about the manufacturer's duty. I wanted to 22 just first address your scientific analysis. 23 That's a separate question that 24 led you to your opinion on the -- your 25 opinion that talc increases the risk of</p>

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Page 330	Page 332
<p>1 ovarian cancer, correct?</p> <p>2 MR. MEADOWS: Objection.</p> <p>3 THE WITNESS: Yes, that's what</p> <p>4 I described. And I thought you were</p> <p>5 talking about duty of the company, and</p> <p>6 so I apologize. I didn't mean to go</p> <p>7 off on a tangent.</p> <p>8 If you want to focus just on</p> <p>9 the risk assessment -- is that what</p> <p>10 you want to do? -- that's what I'm</p> <p>11 doing.</p> <p>12 QUESTIONS BY MR. LOCKE:</p> <p>13 Q. No, I just want to understand,</p> <p>14 those are two different things, though,</p> <p>15 right?</p> <p>16 A. Those are two different --</p> <p>17 those are two different tasks that I</p> <p>18 undertook, yes. I undertook a risk</p> <p>19 assessment task to form opinions based on</p> <p>20 what I can say about risk, and then I</p> <p>21 separately -- and I had done this earlier on</p> <p>22 the issue of warnings, looking at what do we</p> <p>23 know about the product and whether or not --</p> <p>24 and when did we know it, and what should</p> <p>25 consumers have been warned about based on the</p>	<p>1 also sort of -- that's a piece along the way</p> <p>2 to doing a causation analysis, but it's not</p> <p>3 the same.</p> <p>4 Q. Your opinion regarding the</p> <p>5 FDA's responsibilities and functions, that's</p> <p>6 not related to your opinion that talc may</p> <p>7 cause an increased risk in ovarian cancer; is</p> <p>8 that correct?</p> <p>9 MR. MEADOWS: Objection.</p> <p>10 THE WITNESS: I don't think</p> <p>11 that's true the way you're asking that</p> <p>12 question, because I don't know how you</p> <p>13 divorce the fact that as a -- in a</p> <p>14 regulatory assessment, if I identify</p> <p>15 cancer hazard, I have identified a</p> <p>16 duty to warn. That's certainly</p> <p>17 something that should be warned about</p> <p>18 when I understand that there's not</p> <p>19 only the potential, but I believe</p> <p>20 there's an increased risk.</p> <p>21 But I would agree with you that</p> <p>22 in my report, I'm laying out for you</p> <p>23 even different bodies of information</p> <p>24 that -- as I step through it.</p> <p>25 Does that make sense to you?</p>
Page 331	Page 333
<p>1 safety information that was available over</p> <p>2 time.</p> <p>3 Q. The risk assessment task,</p> <p>4 that's what you mean by your analysis that</p> <p>5 talc increases the risk of ovarian cancer?</p> <p>6 A. That's correct.</p> <p>7 Q. You could have stopped at that,</p> <p>8 but then you performed an additional task; is</p> <p>9 that right?</p> <p>10 A. Well, actually, no, because the</p> <p>11 first task I actually started with was the</p> <p>12 regulatory task. When I first started</p> <p>13 getting involved in the litigation very --</p> <p>14 before I wrote my first report, one of the</p> <p>15 first things I was looking at was the issue</p> <p>16 of the duty of the manufacturer to provide</p> <p>17 warnings.</p> <p>18 And then after that, I expanded</p> <p>19 that role to be an inclusion as well of a</p> <p>20 causation analysis.</p> <p>21 And then now I'm not doing a</p> <p>22 full causation analysis in this litigation,</p> <p>23 but I'm using essentially some of the same</p> <p>24 information to provide you with a description</p> <p>25 of a -- a health risk assessment, which was</p>	<p>1 QUESTIONS BY MR. LOCKE:</p> <p>2 Q. Not really.</p> <p>3 A. I'm sorry.</p> <p>4 Q. I'm talking about your</p> <p>5 scientific analysis here, not your regulatory</p> <p>6 analysis.</p> <p>7 To do your scientific analysis,</p> <p>8 you looked at scientific materials, right?</p> <p>9 A. Yes, but I do the same thing</p> <p>10 for my regulatory analysis. That's why I'm</p> <p>11 confused. I -- to me they are connected.</p> <p>12 But I would agree with you, I</p> <p>13 had an analysis. Let's just talk about that,</p> <p>14 my analysis on risk assessment and my</p> <p>15 opinions that I've expressed. Those are laid</p> <p>16 out in a separate section of my report,</p> <p>17 absolutely. So we could talk about that if</p> <p>18 you'd like.</p> <p>19 Q. Well, I just want to</p> <p>20 understand, and I think I do now, that's a</p> <p>21 separate issue from your regulatory opinion?</p> <p>22 A. It's not a separate issue.</p> <p>23 That's where I'm having trouble with your</p> <p>24 language.</p> <p>25 It's a separate task because,</p>

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Page 334	Page 336
<p>1 for example, I may have only been asked, but 2 I wasn't, to just describe whether or not, as 3 a human risk assessor and toxicologist, there 4 is a hazard or a risk posed by the product, 5 and I could stop there. 6 But I was asked, based on -- 7 based on my experience working in the area of 8 regulatory toxicology but also on regulatory 9 issues for clients where I give advice, I was 10 asked to look at how does that scientific 11 information impact what the company should be 12 doing. 13 And so that's -- that's why I'm 14 saying you can't divorce them, because the 15 warning issue I'm talking about is intimately 16 tied into the human health risk assessment 17 results. 18 Q. So do you consider yourself 19 primarily here as a warning expert? 20 MR. MEADOWS: Objection. 21 THE WITNESS: I consider that 22 one of my roles, yes, absolutely. 23 It depends upon how individual 24 cases, individual attorneys, will -- 25 will ask -- decide to use me. For</p>	<p>1 But I practice in both those areas in 2 my consulting practice and in my 3 experience. 4 QUESTIONS BY MR. LOCKE: 5 Q. Let me ask you a few questions 6 about your cosmetic ingredient review 7 statements, CIR. 8 We can agree to call it that, 9 right? 10 A. Yes, that's fine. 11 Q. In parts of your report, you 12 cite the CIR as an authoritative source on 13 cosmetic ingredients; is that correct? 14 A. So where are you looking at, 15 the background information on the CIR? 16 Yes, they certainly are a 17 source of information that FDA relies upon as 18 far as assessments, yes, that's true. 19 Q. Well, and on page -- or 20 paragraph 35, page 23, you cite to the CIR 21 on, for example, chemicals purportedly in 22 cosmetics. You have a footnote there. 23 A. So -- 24 Q. I believe it's footnote 31. 25 A. Yes, I have looked at -- looked</p>
Page 335	Page 337
<p>1 example, I have been used in one trial 2 to only talk about the toxicology. 3 Other trials, I've talked about 4 toxicology as well as regulatory 5 issues. So I think it just depends on 6 the case. 7 In the MDL, I am prepared, 8 however, to come to talk at a trial on 9 the regulatory system that guides 10 cosmetics as well as provide opinions 11 that talk about what are the hazards 12 of talc, what is the toxicology of 13 talc, what do -- how can you be 14 exposed to talc, that migration issue, 15 and then my opinions about whether or 16 not I believe that there is an 17 increased risk of ovarian cancer. 18 So I would be -- be prepared to 19 talk about both of those things. 20 That's why I said I do think I'm a 21 little different than some of the 22 other experts that you may encounter, 23 for example, in the defense side, 24 where someone may just do regulatory 25 or somebody may just do toxicology.</p>	<p>1 at the CIR as a source of information because 2 many of the chemicals, many of the 3 ingredients within the fragrance of Johnson & 4 Johnson, the only available information may 5 be found within the CIR that's publicly 6 available. 7 Q. And you rely on the report of 8 Dr. Cralley; is that correct? 9 MR. MEADOWS: Objection. 10 MS. PARFITT: Objection. 11 QUESTIONS BY MR. LOCKE: 12 Q. You reference Appendix D to 13 your report. I believe if you stay on the 14 same page you'll see that, the same 15 paragraph. 16 A. I wouldn't say I rely on the 17 report of Dr. Cralley because I form my 18 opinions independent of Dr. Cralley, but 19 certainly his -- I believe if you go to his 20 reports, his report is supportive of my 21 opinions in this area. 22 Q. Did you read his report? 23 A. I have read it now, but I did 24 not read it before I -- before I formed my 25 opinions in this particular paragraph, yes.</p>

Confidential - Pursuant to Protective Order

Page 338	Page 340
<p>1 Q. I'm a little confused because</p> <p>2 you're citing to his report.</p> <p>3 You read it or you didn't read</p> <p>4 it before you wrote this paragraph?</p> <p>5 A. I read it before I wrote the</p> <p>6 paragraph. I didn't read it before I had</p> <p>7 formed the opinion. Do you understand what</p> <p>8 I'm saying?</p> <p>9 I did my review of the irritant</p> <p>10 chemicals independently before I looked at</p> <p>11 Dr. Cralley's report. So I had formed the</p> <p>12 opinion that -- of the chemicals I had</p> <p>13 searched for that this is what I identified.</p> <p>14 And that's what this is talking about, right?</p> <p>15 I'm saying here that of the</p> <p>16 more than 100 chemicals included, over</p> <p>17 70 percent are compounds linked with some</p> <p>18 level of irritant hazard. That was done on</p> <p>19 my own.</p> <p>20 Then, if you go to look at</p> <p>21 Dr. Cralley's report, I cite it here because</p> <p>22 it's consistent. That is, his report</p> <p>23 provides support additionally for the</p> <p>24 statement I'm making.</p> <p>25 So I'm not relying on his</p>	<p>1 is no other source available.</p> <p>2 Q. Okay. In your report you state</p> <p>3 that the CIR process is administered</p> <p>4 independent of the FDA.</p> <p>5 But the FDA is on the CIR</p> <p>6 steering committee; is that correct?</p> <p>7 A. That is correct.</p> <p>8 Q. You don't mention that in your</p> <p>9 report, although you mention others who were</p> <p>10 on the CIR steering committee, correct?</p> <p>11 A. Yes, there's a paragraph where</p> <p>12 I talk about others, yes.</p> <p>13 Q. But you don't mention that the</p> <p>14 FDA is on the steering committee?</p> <p>15 A. I believe I -- I believe I've</p> <p>16 been asked that question before, and I said</p> <p>17 yes, but certainly in this report I don't</p> <p>18 believe I state that, that is true.</p> <p>19 Q. CIR solicits input from the</p> <p>20 public; is that correct?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 THE WITNESS: I would say they</p> <p>23 solicit input from industry, yes.</p> <p>24 QUESTIONS BY MR. LOCKE:</p> <p>25 Q. Well --</p>
Page 339	Page 341
<p>1 conclusions to make my opinion, but it's</p> <p>2 certainly -- I am citing it here as it being</p> <p>3 a piece of evidence that is consistent with</p> <p>4 my opinions.</p> <p>5 Q. Sorry, I seem to have messed up</p> <p>6 my microphone. I'll try to hold it for a</p> <p>7 little bit then.</p> <p>8 Do you disagree with</p> <p>9 Dr. Cralley's report?</p> <p>10 A. I have not formed an opinion</p> <p>11 that I agree or disagree. He -- with his --</p> <p>12 I believe he has information that is</p> <p>13 consistent with the opinion I'm expressing in</p> <p>14 the sentence, however.</p> <p>15 Q. And do you know that</p> <p>16 Dr. Cralley repeatedly cites to the CIR as an</p> <p>17 authoritative source regarding cosmetic</p> <p>18 ingredients?</p> <p>19 A. I don't know that he uses that</p> <p>20 exact language, but he does cite to it, yes,</p> <p>21 in his report. Certainly he does.</p> <p>22 Q. More than 20 times, right?</p> <p>23 A. That, I have not counted. I</p> <p>24 can't tell you that. But he does, just like</p> <p>25 I do, as a source of information when there</p>	<p>1 A. But they -- and they do have a</p> <p>2 public comment period, which is mainly input</p> <p>3 from industry.</p> <p>4 But I agree that they do -- and</p> <p>5 if what you're referring to is a public</p> <p>6 comment period, yes, there is that for the</p> <p>7 documents.</p> <p>8 Q. You can go on the website and</p> <p>9 see what ingredients CIR is going to review,</p> <p>10 right?</p> <p>11 A. Yes, you can.</p> <p>12 Q. Have you done that?</p> <p>13 A. Yes, I've done it many times</p> <p>14 before.</p> <p>15 Q. Okay. And did you submit</p> <p>16 comments on talc in 2012?</p> <p>17 A. No, I did not.</p> <p>18 Q. Okay. You could -- the public</p> <p>19 can submit comments many times during the</p> <p>20 process of an ingredient review; is that</p> <p>21 correct?</p> <p>22 A. There are different --</p> <p>23 different stages of the draft document. Is</p> <p>24 that what you're asking me? Yes, that can be</p> <p>25 done.</p>

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Page 342	Page 344
<p>1 Q. Well, even before it's a draft, 2 CIR is soliciting information about the 3 ingredient to include in the initial 4 materials provided to the expert panel; isn't 5 that correct? 6 A. Technically I believe that is 7 true, but I would disagree that that is 8 something that happens routinely. But I 9 would agree that -- I would say technically 10 you may be -- that is something that could 11 occur, yes, but that is not the situation, 12 for example, in the case of talc. 13 Q. Why not? 14 A. Based upon what I have seen 15 described as how the review was done, and 16 that has to do with the testimony of 17 different -- or different documents that I've 18 reviewed and the testimony of individuals 19 related to this document. 20 Q. Well, Dr. Cramer could have 21 submitted comments to the CIR regarding talc, 22 couldn't he? 23 MR. MEADOWS: Objection. 24 MS. PARFITT: Objection. 25 THE WITNESS: You'd have to ask</p>	<p>1 submitted. 2 Q. And CIR meetings are open to 3 the public, right? 4 A. That is true, they are open to 5 the public, but in my experience it -- they 6 are not meetings that are heavily attended by 7 the public but indeed are -- tend to be 8 meetings attended by industry stakeholders 9 within the ingredients that are being 10 reviewed. 11 Q. You know Mr. Steinberg here. 12 He was a plaintiff's expert for a while? 13 A. I don't know him personally, 14 but I know his name and I know he was a 15 plaintiff's expert, yes. 16 Q. You know he attended the talc 17 meeting, right? 18 A. Yes, I believe he was working 19 with indus -- he works with industry, so I 20 believe indeed he did attend that meeting. 21 Q. You're not claiming he was 22 working with any industry member regarding 23 talc, are you? 24 A. That's not what I stated. I 25 know he's a consultant to the cosmetic</p>
Page 343	Page 345
<p>1 Dr. Cramer if he was aware that they 2 were reviewing it. I can't answer 3 that for Dr. Cramer. 4 But if he was aware of it, 5 certainly -- if you're aware of the 6 process going on and the timing of it, 7 certainly you can submit comments. 8 I'm not disagreeing with you on that. 9 That is true. 10 QUESTIONS BY MR. LOCKE: 11 Q. CIR publishes in advance what 12 it's going to review; isn't that correct? 13 A. What is coming up for review? 14 Q. Yes. 15 A. Yes, things that are proposed 16 for the next meeting, yes, that's true. 17 Q. And you could submit comments 18 to the first draft of the CIR report; isn't 19 that correct? 20 A. I would agree that that is 21 possible to happen, yes. 22 Q. And you can submit comments 23 before the final report is drafted, correct? 24 A. Yes, as long as it's still in 25 draft form, yes, those comments can be</p>	<p>1 industry, so it doesn't surprise me. And I 2 believe he lives in the area, so it doesn't 3 surprise me that he attended. 4 I haven't spoken to him about 5 any of that, though, so I have no specific 6 details of that. 7 Q. Transcripts of the meeting are 8 available to the public, right? 9 A. You can download the 10 transcripts, yes. 11 Q. They're on the website? 12 A. That's what I said. You can 13 download. I'm sorry. 14 Q. Okay. 15 A. Yes, you can download them from 16 the website. 17 Q. Did you submit comments to the 18 CIR regarding talc? 19 A. No, I did not. 20 Q. Why not? 21 A. I wasn't aware of the process 22 that was going on in the draft form at the 23 time. 24 Q. Why is that? 25 A. I was not following the CIR for</p>

Confidential - Pursuant to Protective Order

Page 346	Page 348
<p>1 talc at that particular time. I have a lot 2 of other clients and a lot of other issues 3 that go on on a routine basis, and I -- I 4 literally would not have time to follow every 5 assessment they do, considering that they do 6 thousands of chemicals. 7 Q. Did you know of the CIR prior 8 to your retention by plaintiff's counsel? 9 A. Yes. In fact, I -- one of the 10 journals that I receive, International 11 Journal of Toxicology, maybe, publishes many 12 of their safety assessments. So I certainly 13 am, yes. 14 I was aware -- when I was at 15 Evirion, I was aware of the existence of CIR. 16 Q. Have you ever provided prior to 17 this litigation -- and by "this litigation" I 18 mean any aspect of the talc litigation -- an 19 expert opinion on cosmetics' ingredients? 20 A. You're asking me in any other 21 litigation on a cosmetic ingredient? 22 I'm thinking back to the cases 23 I've worked on. Not as a -- not as a 24 testifying expert. 25 At Evirion, though, we worked on</p>	<p>1 same level of review of any of these 2 ingredients as can be provided -- as was 3 provided by the IARC. 4 And so, again, that's one of 5 the comparisons I'm doing. I'm talking about 6 the difference in the time, the effort, the 7 difference in the independence of the 8 reviews. And so that -- when I'm talking 9 about, those numbers, that's what I'm 10 focusing on. I'm focusing on the fact that 11 you have so many reviews in a very short 12 period of time, with a one-expert panel, it's 13 impossible for that level of analysis and 14 review to be anywhere near what IARC panels 15 do, and also nowhere near the level of review 16 that I have done based on the number of 17 documents that I have analyzed and looked at. 18 So it's a different type of review. 19 Q. Let me ask you a few questions 20 because you have criticized the panel. 21 You would agree with that, 22 correct? 23 A. Yes. Oh, absolutely. This 24 particular analysis I have. I have made some 25 general criticisms of the overall process,</p>
Page 347	Page 349
<p>1 litigation involving cosmetic ingredients, 2 thought I was not the testifying expert. 3 Q. In your report you talk about 4 the percentage of -- or the number of 5 ingredients that the CIR listed as unsafe. 6 Do you recall that? 7 A. Yes. I mean, if you want me to 8 verify the number, I need to go there. But, 9 yes. 10 Q. You don't mention that CIR has 11 put limitations on approximately 50 percent 12 of the ingredients that it has reviewed, do 13 you? 14 A. I don't mention that, but they 15 do. They have -- they have -- when they have 16 a statement about safety, they will -- they 17 will often talk about the limitations from 18 the safe use based on either concentration or 19 even maybe route of exposure, that is true. 20 Q. Why don't you do that? Why 21 didn't you include that in your report? 22 A. No particular reason. I mean, 23 the point I'm trying to make is really the 24 workload that's going on here and the 25 impossibility of the task of providing the</p>	<p>1 and then I made some specific criticisms of 2 this particular review. 3 Q. And one of your criticisms is 4 that the CIR -- I think you said two CIR 5 expert panelists had conflicts of interest; 6 is that correct? 7 A. Yes, that -- they did, that 8 were not -- that were not -- I believe not 9 understood even by Dr. Andersen at that time. 10 I think these are things brought up to him 11 that he was not aware of. 12 Q. All right. Now, you read his 13 testimony in one of the trials in California, 14 right? 15 A. Yes, that's the -- in fact, 16 that's the source of the information where 17 I'm citing to those names of those 18 individuals. I think I refer to that, his 19 trial testimony. 20 Q. And didn't he, though, say, 21 well, he didn't view it as a conflict of 22 interest because the money wasn't going to 23 them personally, it was going to their 24 organizations? 25 A. He did make that statement,</p>

Confidential - Pursuant to Protective Order

Page 350	Page 352
<p>1 yes.</p> <p>2 Q. And you disagree with that</p> <p>3 statement?</p> <p>4 A. I don't -- I mean, his</p> <p>5 testimony is what it is.</p> <p>6 Are you asking me do I disagree</p> <p>7 that that's a conflict of interest?</p> <p>8 I disagree that you shouldn't</p> <p>9 disclose that as a potential conflict in the</p> <p>10 documents that are produced, just like I do</p> <p>11 when I write an article and I disclose that</p> <p>12 I've had funding. I don't say what the</p> <p>13 funding specifically paid for, but I've had</p> <p>14 funding or support from this industry</p> <p>15 individual or that industry individual.</p> <p>16 It's -- it's something that just is about</p> <p>17 transparency.</p> <p>18 Q. So when you write articles, you</p> <p>19 say that you've been paid a lot of money by</p> <p>20 plaintiffs' lawyers?</p> <p>21 MR. MEADOWS: Objection.</p> <p>22 MS. PARFITT: Objection.</p> <p>23 THE WITNESS: Well, I haven't</p> <p>24 written an article that overlaps with</p> <p>25 an issue that I've addressed in</p>	<p>1 from an industry or a company that has</p> <p>2 to do with the issue you're looking</p> <p>3 at, yes, a conflict -- a conflict of</p> <p>4 interest absolutely needs to be</p> <p>5 described.</p> <p>6 QUESTIONS BY MR. LOCKE:</p> <p>7 Q. And that would -- well, let me</p> <p>8 just ask you: You're not an ethicist, are</p> <p>9 you?</p> <p>10 A. No, I'm not trained as an</p> <p>11 ethicist.</p> <p>12 Q. And you're not a lawyer, are</p> <p>13 you?</p> <p>14 A. Well, no, but I have passed the</p> <p>15 patent bar, but I'm not trained as a lawyer.</p> <p>16 Q. That doesn't make you an</p> <p>17 ethicist, right?</p> <p>18 A. No, it does not.</p> <p>19 Q. Okay. Let's talk about one of</p> <p>20 the people you criticized, Dr. Wilma</p> <p>21 Bergfeld.</p> <p>22 Did you know she was the first</p> <p>23 woman who was the president -- to be the</p> <p>24 president of the American Academy of</p> <p>25 Dermatology?</p>
Page 351	Page 353
<p>1 plaintiffs' litigation, but I</p> <p>2 certainly have given my conflict of</p> <p>3 interest statements that relate to the</p> <p>4 issue in the article.</p> <p>5 I do that -- I've done that</p> <p>6 with -- on my work -- several of my --</p> <p>7 several of my assessments talking</p> <p>8 about risks of pesticides. I've done</p> <p>9 it with the work that I've done that</p> <p>10 that's been sort of, I guess,</p> <p>11 policy-type work on behalf of the</p> <p>12 American Chemistry Council.</p> <p>13 So absolutely I do.</p> <p>14 QUESTIONS BY MR. LOCKE:</p> <p>15 Q. Okay. You don't think it's</p> <p>16 relevant that you receive 50 percent of your</p> <p>17 money solely from plaintiffs' products</p> <p>18 liability lawyers?</p> <p>19 MR. MEADOWS: Objection.</p> <p>20 MS. PARFITT: Objection. Form.</p> <p>21 THE WITNESS: If it has nothing</p> <p>22 to do with the issue that I'm</p> <p>23 addressing in the paper, no, I do not</p> <p>24 think that.</p> <p>25 But when you're accepting money</p>	<p>1 A. No, I don't know her</p> <p>2 personally, so, no, I did not know that.</p> <p>3 Q. Did you investigate her at all</p> <p>4 when you criticized her?</p> <p>5 A. I wasn't criticizing her, I was</p> <p>6 criticizing the CIR process for failing to</p> <p>7 disclose the conflicts of interest of</p> <p>8 individuals that were involved in their</p> <p>9 assessment.</p> <p>10 I certainly am not giving</p> <p>11 personal criticism to either of those</p> <p>12 individuals.</p> <p>13 Q. You would agree that the</p> <p>14 American Academy of Dermatology is a</p> <p>15 reputable organization?</p> <p>16 A. I haven't formed an opinion one</p> <p>17 way or the other; however, I'm aware of them,</p> <p>18 and certainly I know individuals that are</p> <p>19 members of it, yes.</p> <p>20 Q. Are those individuals reputable</p> <p>21 people?</p> <p>22 MS. PARFITT: Objection.</p> <p>23 THE WITNESS: They are people</p> <p>24 that practice medicine that certainly</p> <p>25 I would go see. I mean, you're asking</p>

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Page 354	Page 356
<p>1 me if I formed a very specific opinion 2 about them as individuals, and I 3 haven't done that. 4 QUESTIONS BY MR. LOCKE: 5 Q. Do you have any reason to 6 believe that the American Academy of 7 Dermatology is disreputable? 8 A. No. Again, I haven't formed an 9 opinion one way or the other. I'm aware of 10 the organization, and it certainly is one 11 that is -- has within its members a number of 12 people that I know that practice in 13 dermatology. 14 Q. Did you know that Dr. Bergfeld 15 was the first woman to be president of the 16 Cleveland Academy of Medicine? 17 A. To the what? What was the 18 first word? 19 Q. Cleveland Academy of Medicine? 20 A. No. Again, I'm not aware of 21 her CV specifically, other than what may have 22 been discussed -- it's possible her -- I know 23 her affiliation will be listed in some of the 24 documents as to where she is today, but I do 25 not know her CV and her history.</p>	<p>1 and also gynecological -- gynecological 2 sciences on the issue of migration. 3 Q. You're not a epidemiologist, 4 are you? 5 A. Not by training. It's a tool I 6 use all the time, but I'm not an 7 epidemiologist by training. 8 Q. And panel members on the CIR, 9 they might have used the same tool that 10 you're using to form your opinion about talc, 11 correct? 12 MR. MEADOWS: Objection. 13 THE WITNESS: Based on what 14 I've reviewed from the minutes and the 15 write-up, I would disagree that that 16 is -- they have done -- they've used 17 the tools in the same way I have. I 18 disagree with that. 19 QUESTIONS BY MR. LOCKE: 20 Q. No, but I'm saying their 21 epidemiology could be the same background 22 that you have. You haven't reviewed who they 23 are, so you really don't really know. 24 MR. MEADOWS: Objection. 25 THE WITNESS: Well, I do</p>
Page 355	Page 357
<p>1 Q. Are you aware that she was the 2 first president -- or she was a president of 3 the American Society of Dermatopathology? 4 A. No. Same thing. If I'm not 5 aware of her CV, I wouldn't know that. 6 Q. How about that she was the 7 former chair to the FDA's drug -- FDA's 8 Dermatology and Ophthalmology Advisory 9 Committee? 10 A. Same answer. I don't know her 11 CV, so I have no knowledge. 12 Q. Is it your opinion that 13 Dr. Bergfeld was not qualified to chair the 14 CIR panel that considered talc? 15 A. I don't think I formed that 16 specific opinion. Instead, what I have -- 17 the opinions I formed relate to the overall 18 makeup of the panel that failed to include 19 individuals with expertise that were -- that 20 are really key to assessing the safety of 21 talc. And that had to do with the issues of, 22 as I discuss it, epidemiology -- oh, I'm 23 sorry, I think I need to put this back -- 24 period -- sorry. In the area of epidemiology 25 is one that I talked about it specifically,</p>	<p>1 know -- I do know Dr. Klaassen, who I 2 believe was on the panel as a 3 toxicologist. He is not somebody 4 that -- he is not somebody that I 5 understand does a significant amount 6 of evaluation in risk assessment for 7 epidemiological studies. He has done 8 some of that, yes, I agree, but it's 9 different training than mine. 10 QUESTIONS BY MR. LOCKE: 11 Q. You're better qualified than he 12 is? 13 A. No, that's not what I'm saying. 14 I'm saying it's different background. 15 The question that I heard you 16 ask me, I believe, was directed towards the 17 differences in my background versus somebody 18 else's. 19 And I'm saying that I'm not 20 aware that he has the same background I do, 21 but there is not -- there was not somebody on 22 the panel that had specific expertise and 23 analysis of epidemiological studies as an 24 epidemiologist. And I think that's important 25 in this case where you're analyzing in a</p>

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Page 358	Page 360
<p>1 causation analysis a wide variety of studies. 2 So I do think it's important. 3 Q. You're not a gynecological 4 oncologist, are you? 5 A. No, I'm not. But again, that 6 would have been an important expertise to 7 have on the panel when -- 8 Q. And yet you formed your opinion 9 with -- 10 MR. MEADOWS: Hold on. 11 MR. LOCKE: No. No. Go ahead. 12 You can ask follow-up questions 13 if you want. 14 MR. MEADOWS: You're 15 interrupting her. 16 MR. LOCKE: Well, I've got a 17 limited amount of time, and I've got 18 to keep moving. 19 MR. MEADOWS: Well -- 20 MR. LOCKE: They're very long 21 answers to questions that I'm not 22 asking. So I -- you follow up if you 23 would like with your questions, but I 24 got to keep moving. 25 MR. MEADOWS: Well, I'm sorry,</p>	<p>1 I'm sorry. 2 Q. The FDA frequently seeks 3 information, scientific information, from 4 cosmetic manufacturers; is that correct? 5 A. I don't understand what you 6 mean by "frequently seeks." They rely on 7 cosmetic manufacturers to do their own safety 8 assessments. 9 Is that what you're referring 10 to? 11 Q. Well, they ask PCPC to comment 12 on scientific issues, correct? 13 A. Yes, I would agree that that 14 interaction has happened, but that's not 15 where the responsibility lies. But I agree, 16 they have. 17 Q. I'm not asking about 18 responsibility. I'm asking: Has the FDA 19 asked cosmetic manufacturers for scientific 20 information? 21 A. Yes, they have in this case. I 22 discuss some of that, yes. 23 Q. And they do that frequently, 24 right? Not just in this case, but generally? 25 A. I can't answer that for all</p>
Page 359	Page 361
<p>1 but you're not going to be allowed to 2 interrupt her. 3 MR. LOCKE: Okay. Then we'll 4 go longer. If she's going to answer 5 questions I'm not asking, then I need 6 to go -- I need to be able to go 7 longer. 8 MR. MEADOWS: You're not going 9 to be allowed to interrupt her. 10 That's just the bottom line. 11 QUESTIONS BY MR. LOCKE: 12 Q. You're not a gynecological 13 oncologist, right? 14 A. I'm not trained as a 15 gynecologic oncologist, that is true. 16 Q. You're not a medical doctor, 17 correct? 18 A. I am not a physician, that is 19 correct. 20 Q. Let's talk about the citizens 21 petition. 22 The FDA frequently seeks 23 scientific information from cosmetic 24 manufacturers; is that correct? 25 A. First part of the question?</p>	<p>1 situations. I have seen it happen before, 2 yes. 3 Q. The FDA asked, for example, for 4 then CTFA to cosponsor the 1994 workshop on 5 talc, correct? 6 A. Yes, they did. 7 Q. The FDA knew that the report 8 prepared by Dr. Huncharek and Dr. Muscat was 9 based on PCPC's retention of those 10 consultants, correct? 11 A. So what are you -- what time 12 period are you talking about? 13 Q. Well, now, there was only one 14 time that Drs. Huncharek and Muscat submitted 15 a report to the FDA regarding talc, correct? 16 A. So I need to look to confirm 17 that. Which time period are you talking 18 about? 19 Q. 2009. Citizens petition. 20 A. Oh, that is true. In the 21 citizens petition, that is true, yes. But 22 I -- but... 23 Q. I mean, it says in the letter, 24 "We're submitting a report written by Drs. 25 Huncharek and Muscat," correct?</p>

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Page 362	Page 364
<p>1 A. In the cover letter from the 2 CRE? 3 Q. From -- not CRE, from PCPC. 4 A. Okay. So let -- I need to -- I 5 need to refresh my memory on the way the 6 submissions were made. I apologize. 7 Do you remember which paragraph 8 that you're referring to? 9 Q. Well, it's throughout your 10 report you're talking about the citizens 11 petition. 12 A. So it's my recollection, based 13 upon the documents that I have seen, that it 14 was not a transparent process at all times 15 that Drs. Huncharek and Muscat were being 16 identified as independent consultants and 17 were not ones that were being actually paid 18 by the industry for some of the work that 19 they did. And I think that's discussed in my 20 report. 21 Q. Well, let's break that down. 22 A. If you want me to confirm the 23 issue of the 2009 -- if you will point me to 24 where you say I discuss this, I will confirm 25 that or not.</p>	<p>1 Q. And you're not aware of any 2 other document indicating that PCPC ever 3 hired Drs. Huncharek or Muscat? 4 A. So that's where I'll need to go 5 back and look at the documents, because -- 6 that I have discussed. So I need to find 7 that on my paragraph. 8 If you want to go off the 9 record for a minute so I don't waste your 10 time, I will look. 11 Q. Sure. 12 A. It's up to you. Or we can stay 13 on the record. 14 MR. LOCKE: I'm fine going off. 15 VIDEOGRAPHER: We are going off 16 the record at 4:23 p.m. 17 (Off the record at 4:23 p.m.) 18 VIDEOGRAPHER: We are back on 19 the record at 4:25 p.m. 20 QUESTIONS BY MR. LOCKE: 21 Q. The question I asked: Are you 22 aware of any other document indicating that 23 PCPC ever hired Dr. Huncharek and Muscat 24 other than for the 2009 response or 25 submission to the citizens petition?</p>
Page 363	Page 365
<p>1 Q. Well, let me break it down. 2 Citizens petition submitted in 3 2008, right? 4 A. Well, there were two: one in 5 1994 and another -- I'm sorry, 1992, and 6 another in 2008. 7 Q. Well, there are actually 8 several more than that, but let's just focus 9 on the 2008. 10 In 2008, a citizens petition 11 was submitted? 12 A. Yes, that is true. 13 Q. And PCPC responded to that 14 citizens petition in 2009, correct? 15 A. They submitted comments. Is 16 that what you're asking me? Yes, they did. 17 Q. Yes. 18 And that was a cover letter, 19 correct? 20 A. A cover letter -- that's all it 21 was was a cover letter? 22 Q. Well, attached to the cover 23 letter was a report from Drs. Huncharek and 24 Muscat? 25 A. Yes, that is true.</p>	<p>1 A. I would have to pull this 2 document, but in paragraph 90 I make a 3 statement: A 2005 response written by 4 Dr. Muscat says -- this is not '09, this is 5 2005, and Dr. Huncharek critiqued the work of 6 Dr. Cramer, who also failed to disclose the 7 financial relation -- I'll start over. 8 Okay. So I'm sorry to repeat 9 myself, but there was a little noise. 10 You asked 2009. So the other 11 time period I have in my report in 12 paragraph 90 talks about 2005, but I'd have 13 to pull this document. 14 But I am citing to the 15 deposition of Dr. Loretz, who was a PCPC 16 employee, so I think I would need to pull 17 this in order to confirm. 18 But I see depositions of her 19 and Dr. Nicholson as talking about them 20 failing to disclose the financial 21 relationship between their work and industry. 22 Q. So if Dr. Loretz did not 23 testify that PCPC had retained Drs. Huncharek 24 and Muscat in 2005, you'd have no other 25 evidence?</p>

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Page 366	Page 368
<p>1 A. I can't answer that</p> <p>2 definitively, but this is what I would point</p> <p>3 you to. So I'd have to pull these documents</p> <p>4 to confirm, but I have -- both paragraphs 89</p> <p>5 and 90 address these general issues for you,</p> <p>6 but I think that's the sentence and the</p> <p>7 documents that I think would be relevant.</p> <p>8 But I'd have to pull them to fully answer</p> <p>9 your question.</p> <p>10 Q. The reason I ask the question</p> <p>11 is because you frequently say "the cosmetics</p> <p>12 industry" without identifying a party or a</p> <p>13 person. And -- well, I'll just leave it at</p> <p>14 that.</p> <p>15 A. And I guess the reason I'm</p> <p>16 saying I need to -- I'm questioning that it</p> <p>17 doesn't have to do with PCPC is because I am</p> <p>18 citing to a deposition of their employee. So</p> <p>19 I need to -- I would -- to affirm it, though,</p> <p>20 I'd need to -- I don't want to say that</p> <p>21 100 percent the answer to your question is</p> <p>22 this is the evidence, but I believe that I</p> <p>23 would need to go here to confirm one way or</p> <p>24 the other. But certainly I would -- this</p> <p>25 raises suspicion about that for me.</p>	<p>1 Q. What evidence do you have of</p> <p>2 that?</p> <p>3 A. Based upon the close</p> <p>4 interaction between PCPC, Imerys and Johnson</p> <p>5 & Johnson throughout these time periods when</p> <p>6 different actions were being taken to comment</p> <p>7 or to submit information on behalf of</p> <p>8 industry.</p> <p>9 Q. Do you have a single document</p> <p>10 you can point to or is that an assumption?</p> <p>11 A. That is something I seem to</p> <p>12 remember based on my review of these</p> <p>13 documents, but if you need a document, I</p> <p>14 would have to -- have to go and look for it.</p> <p>15 Q. Sitting here today, you can't</p> <p>16 recall?</p> <p>17 A. I can't give you a specific</p> <p>18 document as I sit here today, no.</p> <p>19 MR. LOCKE: I have no further</p> <p>20 questions.</p> <p>21 MR. MEADOWS: Yeah, short</p> <p>22 break. Maybe we're done, maybe we're</p> <p>23 not.</p> <p>24 VIDEOGRAPHER: We are going off</p> <p>25 the record at 4:30 p.m.</p>
Page 367	Page 369
<p>1 Q. You have no evidence that PCPC</p> <p>2 ever retained the Center for Regulatory</p> <p>3 Effectiveness; is that correct?</p> <p>4 A. I believe my evidence is hiring</p> <p>5 through Imerys, but let me look to make sure</p> <p>6 that is true.</p> <p>7 Q. Why don't you look at page --</p> <p>8 or I'm sorry, paragraph 95, page 63.</p> <p>9 A. That's where I am. That's</p> <p>10 where I am, so let me read what I have here</p> <p>11 because it's been a while since I've read</p> <p>12 this paragraph.</p> <p>13 So the question is, do I have</p> <p>14 in evidence this paragraph that PCPC directly</p> <p>15 hired the CRE?</p> <p>16 No, that is not provided by</p> <p>17 this paragraph.</p> <p>18 Q. Okay.</p> <p>19 A. However, in this paragraph,</p> <p>20 based on these documents that I'm seeing and</p> <p>21 I'm -- my memory of what is discussed,</p> <p>22 certainly I believe PCPC would have been</p> <p>23 aware of the interaction of CRE at these time</p> <p>24 points when I'm talking about this event --</p> <p>25 these events.</p>	<p>1 (Off the record at 4:30 p.m.)</p> <p>2 VIDEOGRAPHER: We are back on</p> <p>3 the record at 4:45 p.m.</p> <p>4 CROSS-EXAMINATION</p> <p>5 QUESTIONS BY MS. PARFITT:</p> <p>6 Q. All right. Dr. Plunkett, good</p> <p>7 afternoon. I know it's been a long day.</p> <p>8 Dr. Plunkett, you were asked</p> <p>9 throughout the course of the day about</p> <p>10 different constituents which are part of the</p> <p>11 talcum powder products.</p> <p>12 Do you recall those questions?</p> <p>13 A. Yes.</p> <p>14 Q. All right. If -- without going</p> <p>15 through each and every one of different</p> <p>16 constituents that we've talked about that are</p> <p>17 contained or could be contained in the talcum</p> <p>18 powder products, if they are present, do</p> <p>19 those various constituents present and</p> <p>20 provide biologically plausible evidence that</p> <p>21 talcum powder products can increase the risk</p> <p>22 of ovarian cancer?</p> <p>23 MS. BOCKUS: Object to the</p> <p>24 form.</p> <p>25 THE WITNESS: Yes, which is --</p>

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<p style="text-align: right;">Page 370</p> <p>1 I think I have a couple of paragraphs 2 where I talk about that issue. It has 3 to do -- there's other information as 4 well, but that is a key piece of that 5 information. And I focused on mode of 6 action and additivity. That's on 7 mechanism, biologic plausibility. 8 So the fact that you have a 9 variety of constituents that have a 10 known cancer hazard that share a mode 11 of action, that increases your 12 confidence in the biologic 13 plausibility of that relationship 14 between ovarian cancer and exposure to 15 talc body powders, yes. 16 MS. PARFITT: Thank you. I 17 have no further questions. Thank you 18 very much, Dr. Plunkett. And a happy 19 holiday to you. 20 THE WITNESS: Thank you. 21 MS. BRANSCOME: I have no 22 questions. 23 MS. BOCKUS: No questions. 24 VIDEOGRAPHER: The time now is 25 4:47 p.m. This concludes the</p>	<p style="text-align: right;">Page 372</p> <p>1 CERTIFICATE 2 3 I, CARRIE A. CAMPBELL, Registered 4 Diplomate Reporter, Certified Realtime Reporter and Certified Shorthand Reporter, do 5 hereby certify that prior to the commencement of the examination, Laura Plunkett, Ph.D., 6 DABT was duly sworn by me to testify to the truth, the whole truth and nothing but the 7 truth. 8 I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the 9 testimony as taken stenographically by and before me at the time, place and on the date 10 hereinbefore set forth, to the best of my ability. 11 I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney 12 nor counsel of any of the parties to this action, and that I am neither a relative nor 13 employee of such attorney or counsel, and that I am not financially interested in the 14 action. 15 16 17 18 CARRIE A. CAMPBELL, NCRA Registered Diplomate Reporter 19 Certified Realtime Reporter California Certified Shorthand Reporter #13921 20 Missouri Certified Court Reporter #859 Illinois Certified Shorthand Reporter 21 #084-004229 Texas Certified Shorthand Reporter #9328 22 Kansas Certified Court Reporter #1715 Notary Public 23 24 Dated: 12/20/18 25</p>
<p style="text-align: right;">Page 371</p> <p>1 deposition, and we are going off the 2 record. 3 (Deposition concluded at 4:47 p.m.) 4 ----- 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 373</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. 5 You should state the reason in the 6 appropriate space on the errata sheet for any 7 corrections that are made. 8 After doing so, please sign the 9 errata sheet and date it. You are signing 10 same subject to the changes you have noted on 11 the errata sheet, which will be attached to 12 your deposition. 13 It is imperative that you return 14 the original errata sheet to the deposing 15 attorney within thirty (30) days of receipt 16 of the deposition transcript by you. If you 17 fail to do so, the deposition transcript may 18 be deemed to be accurate and may be used in 19 court. 20 21 22 23 24 25</p>

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Page 374		Page 376	
1	ACKNOWLEDGMENT OF DEPONENT	1	-----
2		2	LAWYER'S NOTES
3		3	-----
4	I, _____, do	4	PAGE LINE
5	hereby certify that I have read the foregoing	5	_____
6	pages and that the same is a correct	6	_____
7	transcription of the answers given by me to	7	_____
8	the questions therein propounded, except for	8	_____
9	the corrections or changes in form or	9	_____
10	substance, if any, noted in the attached	10	_____
11	Errata Sheet.	11	_____
12		12	_____
13	_____ Laura Plunkett, Ph.D., DABT DATE	13	_____
14		14	_____
15	Subscribed and sworn to before me this	15	_____
16	_____ day of _____, 20 _____.	16	_____
17	My commission expires: _____	17	_____
18		18	_____
19	Notary Public	19	_____
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Page 375	
1	-----
2	ERRATA
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Page 377

A	311:10	128:12,13,16	108:7 292:23	agency 43:18,22
a.m 1:15 6:7	acceptable	178:9 179:14	296:2	284:3
25:10,11,13	119:25 311:22	179:21 242:19	addressing	agent 38:15,17
94:23,24 95:1	accepted 78:15	add 21:2 53:19	130:25 193:14	39:20 220:25
99:22,23,25	98:13 297:8	228:21	351:23	221:3 234:22
abbreviation	accepting	added 47:10	adds 168:19	264:6
108:4	351:25	54:14 68:1	adequate 112:14	ago 28:25 288:9
ability 46:12	access 57:13	122:6 146:13	112:18	agree 45:21 59:5
64:23 70:5,10	121:17 123:18	211:25 228:19	administered	73:13 78:9
72:10 185:5	144:11 163:12	308:23	340:3	81:25 91:20
210:13 213:20	164:13 246:7	addition 53:15	administration	106:20 135:24
223:7,10	246:12	123:14 215:1	242:14	142:24 152:2
254:11 273:23	accessibility	270:3	admit 134:24	154:13 157:2
277:7 278:22	264:24	additional 10:3	admitting	159:2,8 173:15
372:10	account 95:17	10:7 17:20	134:24	175:2,8 179:7
able 39:8 42:15	100:5 131:12	20:22 21:2,6	adopted 213:12	179:13,15
51:17 61:3	131:19,22	21:10,12,14,18	advance 122:5	180:2,4 181:3
70:22 92:23	228:14 243:24	21:20 27:5	343:11	195:1,8 198:6
123:19 125:6	246:18	32:12 33:14	adverse 128:2	203:5 207:16
158:23 172:18	accumulated	55:14 68:15,16	139:4 140:16	210:5 213:4,11
172:22 196:1	30:8	81:12 82:15	140:20 236:12	214:12 227:3
225:1,10 226:5	accurate 66:13	94:7 97:14	242:15,22	228:13,24
231:13 235:23	66:15 315:25	146:17 301:20	294:10	232:18 233:23
239:5 265:23	316:6 322:22	331:8	advertising 44:8	234:20 238:8
282:15 291:25	373:18	additionally	advice 44:13	241:11,24
292:3 301:16	acknowledge	338:23	45:10,12,25	254:17 264:4
305:24 359:6	105:18	additive 275:25	46:2,5,8,13	264:13,15
absence 261:9	ACKNOWLEDGE...	278:3 289:10	202:20 334:9	270:16 279:9
absolutely 60:18	374:1	289:18 291:6	advise 45:17	287:25 293:25
72:6,24 171:9	ACOG 192:3	292:14	297:15	294:7,14,23
204:23 213:10	act 265:24	additivity	advising 45:13	295:1,9,20
223:12 232:4	action 268:10	146:14 167:3	Advisory 355:8	307:20 308:3
247:6,21 293:7	275:23 278:6,6	225:6 278:7	affect 72:10 99:3	309:9 311:1,6
294:14 299:15	289:8 292:25	289:5 293:2	125:25 128:1	318:5 319:16
304:22 305:3	295:5 370:6,11	370:6	150:7 168:18	319:21 320:2,6
314:2 320:3	372:12,14	address 29:5	affiliated 26:9	324:15 332:21
325:23 333:17	actions 368:6	30:20 73:23	affiliation 245:7	333:12 336:8
334:22 348:23	active 27:12	78:5 134:17	354:23	339:11 341:4
351:13 352:4	246:22	179:2 182:24	affiliations	342:9 343:20
abstract 314:2	activities 31:6	217:10 220:11	245:2	348:21 353:13
abstracts 313:18	activity 317:23	244:12 329:22	affirm 366:19	357:8 360:13
313:22 315:1	actual 26:1 66:2	366:5	afternoon 19:5	360:15
Academy	103:13 108:23	addressed 97:10	201:2,4 287:16	ahead 13:5,13
352:24 353:14	121:18 166:22	275:2 287:24	369:7	13:15 358:11
354:6,16,19	170:15 277:21	350:25	age 7:21	air 177:14,16
acceptability	288:15,16	addresses	agencies 244:4	al 4:20
	acute 126:5	103:17 105:4	269:6 290:13	Alabama 2:6

Alexandria 2:10	96:4 113:17	anatomy 216:13	139:19 140:5	4:3
align 194:24	114:12 116:25	302:14	141:4 146:23	appears 65:19
195:24	117:25 119:15	and/or 128:2	159:22 192:10	172:10
allege 275:11	124:5 131:12	277:9	193:24 210:14	appendix 63:22
alleged 126:21	131:16 137:4,7	Andersen 349:9	217:16 218:16	63:22 337:12
Allen 2:2 3:18	139:12 143:1,4	Anderson 250:3	222:12 226:1	apples 120:8
allow 82:18	143:9,10 144:3	Angeles 2:23	229:17 232:7	applicable
144:3 158:9	144:8,14 161:5	animal 36:14	250:16 263:17	212:21
172:6 182:13	161:24 162:4	37:15 68:5	273:16,20	application
185:23 229:17	162:22,23	69:13 71:25	288:4,8 300:22	36:17 37:3
230:3 232:8	163:8 164:16	88:4,14 101:10	308:18 309:6	64:24 67:10,16
237:12 240:9	165:20 176:9	101:16,25	318:19 343:2	175:13 177:17
240:13 300:18	176:10,20	104:5 115:4	355:10 359:4	181:20 184:12
allowable	177:1,1 185:16	117:9 118:6,9	360:25 366:1,8	184:20 185:19
311:14	201:17 203:12	142:6 156:16	366:21	186:8 203:22
allowed 328:19	203:17 205:2	172:18 182:11	answered 45:2	212:22 214:15
359:1,9	207:4 209:14	205:24 207:5	90:14 93:19	264:1 296:21
allows 36:6 41:6	210:2,10,25	207:19 208:5	139:9 141:8	296:22 297:11
176:17	215:8,18,22	208:16 217:1,6	237:7 261:2	299:1,9 300:11
alternative	217:24 218:2,5	218:3,11,11	answering	300:16
202:25	218:18,25	219:7 224:1,2	134:18	applications 5:1
America 3:5	219:13 234:22	229:2 230:17	answers 88:22	200:10 211:12
American 247:9	235:4,5,7	230:22 231:17	232:6 358:21	295:24 300:12
351:12 352:24	244:24 246:8	231:20,23	374:5	applied 92:21
353:14 354:6	247:21 248:16	232:5,12	anthophyllite	99:8 149:12
355:3	248:23 255:22	237:20 238:22	254:1	173:16 183:3
amount 298:11	259:4 263:17	238:22,23	anticipate	186:7 258:24
299:2 300:14	265:18 266:7	240:7,9,12	176:23	299:5 302:15
306:5 310:19	271:25 275:13	241:13 280:5	Antonio 3:4	applies 41:17
357:5 358:17	275:19 277:13	291:17	anybody 45:15	91:10,13
amounts 129:11	310:16 311:23	animals 101:12	84:12 160:25	298:18
178:5,7,21	313:12 325:16	101:18 220:11	242:2 302:12	apply 38:25 40:1
227:2 311:4	325:18 326:19	220:12 231:9	302:12	90:10 160:21
amphibole	329:22 331:4	232:16 242:15	apart 76:14	207:18 214:3
255:4	331:20,22	270:6,20 271:1	apologize 11:15	278:7
analyses 257:20	332:2 333:5,6	271:8,10	64:8 105:10	applying 259:1
311:20	333:7,10,13,14	279:24 291:21	201:13 251:12	301:2,9
analysis 8:10	348:13,24	answer 24:16,18	298:14 313:15	approach 79:11
31:24 34:7	357:23 358:1	24:22 25:1	319:8,10 323:6	205:21 212:23
35:4,6,15,16	analyze 36:23	37:6 40:20	327:24 330:6	214:16 218:18
36:22 38:4,12	analyzed 138:2	42:16 50:21	362:6	appropriate
41:18 70:25	250:24 251:5	51:9 56:3 60:4	app 185:18	30:11 45:18
71:9,14,21	266:11 348:17	68:13 78:6	apparent 223:6	47:5,16,25
72:4 74:15,17	analyzing	83:8 88:25	appear 28:5	48:20 49:9
74:19 75:2,10	141:14 154:16	92:23 93:20,23	68:3 303:1	50:2,19 51:20
90:10 91:21	217:21 261:7	94:15,17 96:25	315:7	52:19 373:6
93:14 95:5	357:25	112:3 136:5	APPEARAN...	appropriately

239:15	122:21 124:4	23:24 161:13	325:7 326:25	141:22 149:10
approval 186:4	133:9 137:4	180:3 218:25	332:11 341:24	150:7,22 153:9
298:1	184:2 249:25	asked 18:6 29:5	346:20 350:6	153:12 154:24
approximately	250:12,24	29:19 30:3,6	353:25 358:22	154:24 155:2
347:11	286:18 350:18	30:19 31:20	359:5 360:17	157:16 159:23
approximation	articulated	44:7 45:1	360:18 363:16	165:21 169:23
69:4	202:8	50:17 53:17	aspect 256:5	170:21 171:8,9
area 30:14 35:12	asbestiform	54:19 55:1,6	346:18	171:10 173:7
54:24 59:21	147:1,2,15	62:15,19 82:7	aspects 34:2	191:25 193:2
61:16,16 62:4	148:24 149:17	89:1,2 92:9,24	216:19	196:24 197:12
131:1 262:14	151:6 161:12	93:4,12 94:6	asphyxiate	197:13,21
281:5 298:19	161:22 162:13	96:15 154:23	178:24	198:16,16
334:7 337:21	asbestos 57:21	174:6 182:1	asphyxiation	199:5,10,25
345:2 355:24	146:13 148:3,3	201:21,25	178:18,20	201:6,14 202:3
areas 54:15	148:5,11,11	237:8 239:6	assays 257:19	203:13 204:5,8
56:22,22 58:13	162:14 163:17	241:4 273:19	assess 52:25	204:11 205:8
58:14,15 61:21	197:3 221:14	286:14 298:10	140:2 185:23	205:10,11,13
61:24 81:17	224:16,17,22	322:13 323:4	235:22 282:6	205:15,23
94:7 336:1	226:15,18	323:14,17,17	assessed 256:6	206:20 210:12
argue 182:5	248:10 249:16	327:9 334:1,6	319:24	212:20 213:9
224:12 225:25	249:21 250:9	334:10 340:16	assessing 35:21	214:1,4 216:3
327:10	251:9,10	360:19 361:3	115:4 153:16	221:16 230:6
argument	252:14 253:17	364:21 365:10	209:19 235:25	234:17 236:2
188:19	253:18,23	369:8	355:20	238:5 244:20
arising 181:1	254:3,9,20	asking 23:16	assessment 4:22	246:17 255:25
Arlon 250:4	255:3,5,8,12	25:17 28:8,11	16:12 17:8	268:20 271:12
Arndt 3:20 6:3	255:15,17,23	28:15 39:25	31:5 34:20	272:22 275:6
arrived 12:10	256:4,12,21	40:2 41:16	35:11,13,24	275:20,24
arsenic 267:1	257:6,16 258:6	48:25 49:3	36:12,14,18,20	278:8,20 283:3
268:23	258:10,18,19	50:6,7,15,24	36:21 38:3,11	285:8,22
article 26:7	259:4 260:1,11	71:6,8,11,12	39:3 40:24	289:11,14
27:10 60:10	260:12,20,23	102:9 110:1,3	49:21 74:11	291:3,4 294:21
63:4 68:19	261:9 262:7,10	113:23 134:5	75:21,22 76:1	294:24 314:12
69:4,12 99:4	262:11,23	144:2 145:4,5	76:25 77:1	314:23 320:1
135:21 251:17	285:4,5,8,16	168:2 176:15	78:11 79:3,5,6	321:24 323:19
313:25 350:11	286:3,9	203:14 206:12	81:5 82:9	324:11,11,16
350:24 351:4	asbestos-free	210:14 211:1,5	85:22 87:6,22	324:17,20
articles 25:23	223:20 257:22	219:5 225:18	89:6 99:13	325:25 326:15
26:1,4 27:6,22	258:22 260:16	229:12 233:8	107:3 114:20	327:20 328:1,6
59:12,15,24	261:4	233:10,11	115:8,13,17,24	328:9,22
60:20 61:6,18	asbestos-like	234:18 235:1	117:19 120:10	329:18 330:9
62:16 63:11,18	250:10	236:25 260:18	120:11 122:1	330:19 331:3
64:2 68:15,16	asbestos-only	271:1 274:20	122:23,25	331:25 332:14
71:23 83:9	226:11 285:10	277:18 284:22	123:2,5 126:12	333:14 334:16
87:13 98:11,11	ASHCRAFT	298:16 312:12	127:4,12	346:5 353:9
100:14 103:21	2:8	315:12 321:11	135:16 136:6	357:6
121:20 122:19	aside 11:20	321:13,15	138:7,19 141:6	assessment's

assessments 85:9 99:9 115:21 117:5 149:19 209:7 230:20 273:17 277:4,5 329:10 336:18 346:12 351:7 360:8	attack 180:21 attempt 88:25 132:9 160:6 161:10,19 171:1 172:12 182:2 187:13 208:20,24 214:20 224:24 250:22	authorities 66:19 81:22 authority 45:9 82:8 authors 105:21 105:21 117:19 135:1 207:4 209:1 239:19 240:19,24 245:3	187:25 248:14 251:15 261:11 308:9 320:23 320:24 321:3 321:21,25 322:6 343:1,4 343:5 345:21 346:14,15 349:11 353:17 354:9,20 355:1 355:5 357:20 364:1,22 367:23	200:24 215:15 246:15 273:16 276:16 280:4 287:6,22 321:6 321:7 346:22 355:23 364:5 364:18 369:2
assessor 143:16 167:6 334:3	attempted 165:13 215:2 219:5 237:18 240:23 243:9 272:5,6 281:7 295:16 316:1	authorship 245:15		background 157:13 160:4 171:21 172:11 199:13 260:1 286:9 306:25 336:15 356:21 357:14,17,20
assign 78:12 82:21 95:24 97:3,6 105:19 106:10,17 210:20,22	attempts 130:15 attend 344:20 attended 344:6 344:8,16 345:3 attending 11:13 attention 84:17 212:4 253:6 attorney 24:8,14 54:5 372:11,13 373:15	automatically 247:14 availability 283:13 available 21:11 21:13,15 53:23 54:16 62:2 67:3 73:23 86:17 90:25 115:20 118:2 121:22 138:4 139:1 140:2 141:12 156:23 165:23 170:5 172:6,14 187:24 194:10 194:11 197:15 224:13 235:19 237:11 248:20 251:4 253:11 253:13 260:17 276:16 293:24 316:14 328:10 331:1 337:4,6 340:1 345:8	B baby 8:11 10:25 19:9 34:12,18 37:2,2 40:12 41:3 80:4 117:2,24 124:7 126:14 133:21 141:1 143:3 144:7,19 150:25 151:4 153:23 155:17 157:4 160:23 161:13 167:19 169:10 170:8 173:20 176:4 176:23 180:5 188:11 198:2 248:1,5 249:11 249:14,22 250:14 251:16 252:12,15 308:19	badly 232:2 bar 352:15 barriers 232:23 based 18:3 20:24 22:10 28:23 29:11 30:22 32:19 36:8,14 39:5 39:11 40:21 41:23 44:18 48:6,11 49:14 50:22 71:15 82:15 83:21 85:8 86:6,19 87:14 92:10 94:18 98:24 105:15 116:5 117:13 118:3,6 121:5 125:6 126:12 140:1 144:7 146:23 150:14 154:1 156:24 169:23 172:16,22 173:16 174:2 182:7,19 185:6 187:22 191:10 194:19 197:22 205:2,24 207:25 208:4 210:12 215:25 217:15,18,25 223:5 225:9
assigned 79:7 89:3 96:5 134:12 227:8	attended 344:6 344:8,16 345:3 attending 11:13 attention 84:17 212:4 253:6 attorney 24:8,14 54:5 372:11,13 373:15	average 302:8 avoid 129:10 avoiding 202:25 aware 68:10 108:1,5,10,11 109:8 120:24 122:10 131:20 136:9 142:14 154:8 177:17 177:19 178:17		
assisted 25:18 25:21	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			
association 4:19 38:23 112:15 112:17,18,22 119:5 204:1,3 204:17 322:4 326:17	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			
assume 89:9 148:10 261:18 275:23 282:9 294:21	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			
assumed 285:9 317:4	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			
assumption 282:8 368:10	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			
assurance 222:14	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			
assure 223:10	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			
attach 180:14	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			
attached 5:3 363:22 373:11 374:7	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			
attaching 180:19	attorney's 25:4 53:17 attorney-client 23:23 attorney/client 54:4 attorneys 12:8 12:10 18:13 22:14 23:17 25:16,16 53:24 54:19 116:8 334:24			

226:21 233:1	beginning	204:17 206:16	biggest 182:22	369:20
245:2,22 247:3	206:22	207:24 209:8	bill 10:20 11:24	biology 294:17
247:17 250:20	begins 64:2	212:2 213:7	12:1	biopsies 186:2
257:17 258:7	267:13	219:8 222:14	billed 11:24	bit 31:11 35:21
264:4 269:16	behalf 7:24 8:6	223:3 243:21	billing 10:3,7,15	37:8 38:10
270:25 274:15	53:11 246:21	244:2 245:21	17:18 19:23	39:16 42:18
293:16 297:8	248:4 287:10	247:18 248:16	20:14,15,17	53:5 81:18
299:12,17	322:11 351:11	251:18,19	62:22	95:4 165:5
301:11 302:14	368:7	254:23 257:7	bin 118:8,9,10	201:5 339:7
304:25 307:1	belief 31:25	257:15 258:7	217:9,23	Blejer 250:4
309:1 310:15	71:22	269:25 271:20	252:24,25,25	blood 264:12
311:22 315:7	believe 10:1	276:15,17,22	254:5,6	312:3,21,23
316:13 319:25	15:25 17:25	278:10 279:3	binning 216:16	313:3,10
320:7,8 324:8	18:1 19:15,24	280:14 281:19	216:20,25	Blount 163:4,15
327:10 328:10	20:12 29:11	283:7 286:13	217:14	250:2 252:5,11
330:19,25	31:12 32:8	288:8 299:11	bins 118:8 217:2	Blount's 162:9
334:6,7 342:14	33:16 39:9	299:17 300:6,9	217:18 281:7	249:6 251:15
347:18 348:16	41:1 48:3 62:1	300:13 306:20	bioaccessibility	252:2
356:13 361:9	66:14,19 71:16	308:24 314:6	265:2	board 105:14
362:12 367:20	81:4,16 82:3	318:23 332:19	bioaccessible	Bockus 3:1 4:6
368:3,12	83:9 89:23	335:16 336:24	264:8,10,13,18	7:10,10 94:12
basic 35:25	93:19 95:11	337:13,19	264:21	287:15,18
36:18 38:7	96:19 98:9,17	339:12 340:15	bioassay 232:4	292:10 293:10
79:21 274:6	100:8 105:24	340:15,18	biocompatibil...	296:13 297:12
323:17,18,23	106:1,3 108:21	342:6 344:18	266:18	298:15 299:23
basing 49:25	109:3,12,13	344:20 345:2	biologic 34:4	300:19 303:11
284:15	110:15 111:1	349:8 354:6	37:13 77:9	303:17 304:17
basis 50:18,25	119:8 120:8,14	357:2,16	88:9 179:8	306:14 307:18
61:11 98:16	134:17 139:9	366:22 367:4	193:1 194:2,7	308:1,10 309:7
150:12 155:5	141:23 143:15	367:22	194:18 195:9	310:1 312:1,6
200:15,15	143:24 157:12	believed 122:14	195:14,16	312:13 315:20
232:12 258:13	157:23 158:13	273:13	268:11,11	317:1 318:24
271:16 272:1	158:23 160:18	bell 206:5	289:3 314:20	369:23 370:23
280:8 302:3,21	162:6,9 163:18	beneficiation	370:7,12	bodies 31:16
346:3	163:20 173:6	131:13 132:1	biological 106:2	65:5 67:11
Bates 22:6 58:25	175:12 181:15	Bergfeld 352:21	124:14 179:9	161:1 173:11
bathroom 299:7	182:1,9,16,25	354:14 355:13	188:10,25	256:6,19
Baylen 2:14	183:4 185:4	best 110:20	189:16 192:14	332:23
bear 47:4	187:21 188:20	159:21 372:9	194:14 195:2	body 21:23,24
Beasley 2:2 3:18	189:5,6,14	better 110:18	195:12 196:6	22:4 36:5
Beattie 2:4 6:22	190:19 191:3	228:10,11,12	219:23 278:12	41:17,18,19
6:22 18:17	191:10,14,16	230:21 357:11	biologically	63:20 67:15
beauty 145:7	192:6,7,23	beyond 220:14	42:10,11 189:8	78:22 118:21
becoming	196:12 197:18	220:15,22	191:22 194:2,6	121:14 125:18
220:19 223:6	198:19 199:9	235:14 327:19	194:24 196:12	128:18,19
began 23:7	200:12 201:22	bias 245:22	221:19 227:18	129:15 130:14
31:24 317:8	203:24,25	big 263:13	229:14 277:6	146:20 150:10

154:11 161:20	91:6 93:10,24	brief 286:16	107:23 108:2	173:21 176:3
162:25 164:8	94:20 95:2	briefly 17:16	151:2 202:2	179:10,23
170:3 173:9	96:17 99:19	287:23	206:1	180:25 181:12
175:21 192:21	100:1 106:8	bring 9:23 10:2	calling 112:16	188:13 189:1
198:21 219:18	107:7,21 111:6	16:11 157:15	calls 24:16	189:18 190:2
228:4 232:20	111:16,24	201:12 251:13	Campbell 1:16	190:12 191:1
233:17 253:4	113:24 118:23	bringing 105:12	7:18 372:3,17	191:12,23
256:15 265:16	121:19 127:13	brings 77:22	Canada 5:2	192:5,17 193:4
283:1,9 293:18	130:8 131:24	155:1	16:13 17:5	193:5,18
295:14 301:15	133:3 134:8	broad 227:5	117:20 201:6	194:15,23
301:16 306:23	135:19 137:2	broader 29:14	201:14,17,25	196:2,7,22
313:2,9 316:14	137:14 139:7	134:6 326:5	202:10 204:13	198:3,23 200:5
318:3 320:7,9	140:3 142:11	broke 140:7	204:25 205:6	202:12,19
325:24 329:3,4	144:1,20	broken 100:18	205:10 206:20	203:7 204:16
370:15	145:15 146:1	brought 16:20	211:8,12 212:8	207:22 208:23
body's 228:14	155:11 156:20	169:19 349:10	282:23 283:21	220:1 221:3,10
bottle 145:3	158:11 160:1	bucket 324:3	284:13	223:1 227:14
bottom 267:13	161:3 162:20	buckets 323:23	Canada's 4:21	227:21 228:9
318:15 359:10	164:6,15 166:1	329:9	284:7	229:20,21
Bouquet 142:22	167:15 171:16	bullet 15:19,21	Canadian 78:25	232:3 236:20
143:2,14 144:5	174:4,13 176:8	bullets 135:9	79:4 87:12	237:4,15
144:8,13	180:1 181:9	burden 313:2,9	89:11 90:21	238:10,13
145:13 163:21	183:11 185:15	bursal 101:19	91:19,20 93:14	239:19 240:15
164:2,10	187:11 188:1,8		191:25	241:23 254:12
Bradford 74:14	190:22 193:21	C	canal 180:9	254:23 256:8,8
74:17,18,21	196:3,18	C 2:1	cancer 4:20,23	256:23 258:1,4
75:2,9 114:20	199:15 200:19	cadmium 267:2	4:25 34:13,19	260:21 264:8
159:14 194:8	201:1 211:16	268:24,25	34:19 36:13,15	269:1,18,19,23
195:9 196:17	215:14 221:23	calculate 36:15	37:4 40:14	270:12 271:15
brand 164:8	223:23 234:5	calculating	41:4 57:1,1,2	271:16 272:2,3
brands 162:24	234:19 238:19	88:14	57:21 61:17,18	272:13,18,19
Branscome 2:21	241:9 242:6	calculation	61:20,20 62:9	272:25 273:6
4:5 7:14,15 8:2	253:15 255:21	259:7,9 263:25	80:5 86:22	273:10,12,13
8:6,15 13:14	259:11,20	264:3	88:15 107:9,12	273:15,21
13:19 16:18	260:24 261:14	California 1:18	107:17 108:6,8	274:1,13,14,25
17:11 23:19	262:1 263:4	2:23 349:13	109:18 110:5,7	275:7,17,20
24:10,21 25:2	270:23 279:8	372:19	110:13,24,25	276:6,14 278:7
25:6,14 28:16	280:7 282:14	call 30:14 35:14	111:2 112:6,8	279:20,23
29:15 32:14	284:5,24 287:1	54:3 64:6,7	112:24 113:10	281:14,22
33:11 39:14	287:8 370:21	77:1 92:6	119:6 124:6	282:19 285:4
40:3 43:1 45:7	break 76:14	118:7 124:16	125:10,12	285:17 286:5
49:4,24 50:16	94:12,19	252:25 307:24	127:21,23	286:11,19,23
51:15 53:3	100:12,20	309:3,4 310:21	149:19 151:21	288:20,24
56:14 59:4	169:17 287:2	311:13 336:8	156:11,15,18	289:7,14
73:12 74:9	362:21 363:1	called 20:16	157:6,9 158:3	291:11,12,13
75:6 87:1	368:22	26:9 35:11	160:4 165:10	291:18 294:17
88:19 90:2	breaking 137:24	53:17 63:18	169:4 171:23	294:20 306:19

306:24 312:8	7:5	262:17 334:24	195:5	40:23 42:5,23
319:19 321:2	caroline.tinsle...	346:22	causes 34:13	51:25 59:22
322:5 324:7,12	3:13	Cashmere	38:15 110:25	70:18 71:13
324:12,22	Carrie 1:16 7:17	142:22 143:2	220:25 286:18	73:4,24 74:20
325:2,17 326:1	372:3,17	143:14 144:5,7	causing 157:6	76:24 79:13,20
326:5,24 327:6	carried 264:12	144:12 145:13	196:21 208:23	81:25 83:17,19
330:1 331:5	carry 170:23	163:21 164:2	260:20 266:2	85:7 86:5
332:7,15	313:1	164:10	270:13 275:16	87:12 89:22,22
335:17 369:22	carrying 245:13	categories 31:20	caveat 198:24	91:25 98:17
370:10,14	Casarett 289:20	56:19,21 138:8	cell 220:3,7,8	99:11 101:3
cancers 270:8	290:4,5,15,16	208:17,25	221:25 222:4,4	116:20 119:17
271:20,21	290:18	210:7,17	222:9 228:24	123:20 128:23
capability	case 10:10,24	215:17,20,25	233:1,4,14,16	129:25 130:12
140:19 279:22	19:16,18 32:17	categorization	233:24,25,25	135:12 136:9
capable 181:25	40:12,14 60:13	209:24	234:8,10,14,16	137:23 138:1
266:1 275:16	85:13 91:14	categorize	237:21 279:19	138:16 143:12
capacity 312:24	96:12,14 97:11	141:13 210:11	279:20,20	143:13 144:13
carcinogen	97:18 116:8	326:3	281:16	149:9 150:3,6
197:6 271:18	122:8 126:24	category 151:6	cells 224:2	150:21 153:10
280:25 281:21	173:17 226:11	197:8 210:23	228:10,21,22	153:13 155:22
281:24	226:12 230:19	causation 34:1,7	233:10,16,20	158:21,24
carcinogenesis	231:11 232:8	35:1,6,15,15	233:20,21	160:20 162:2,3
227:25 272:12	236:17 237:13	36:21 37:21	281:18	167:5,9 168:5
274:6 277:6	239:3 255:17	38:4,11 39:2	cellular 220:6	169:13 172:23
carcinogenic	268:16 287:19	41:18 79:11	228:16 314:9	173:8 175:18
88:10 148:7	311:7 318:8	119:14 192:16	Center 367:2	177:19,24
197:3,10 198:7	329:2 335:6	203:12,17	certain 12:15	178:1 179:21
220:20 256:3	342:12 357:25	285:18 326:19	15:11 34:2	184:7 185:22
256:10 257:11	360:21,24	331:20,22	38:2 44:15	187:23 191:9
268:18 278:2	case-by-case	332:2 358:1	53:18 77:17	200:12 209:4
279:17,18	98:16 155:5	cause 34:3 37:3	78:14,17,18	216:18 219:3
282:1,19 288:3	case-control	75:14 110:15	84:19 99:1	223:15 227:17
288:13	79:16 113:3	110:16,22	114:15 125:2	227:24 229:21
carcinogenicity	case-specific	128:9 189:1,18	131:7 140:15	230:5 234:13
151:9	304:3 305:7,22	190:11,25	140:16 150:1	235:21 245:4
carcinogens	305:25 306:2	196:6 220:1	151:4 152:17	245:17,20
254:16 256:13	cases 1:7 11:2,5	221:3 254:12	153:3,5 159:17	246:24 248:19
256:17 269:7	11:9,19 19:19	264:22 269:17	175:10 190:1	249:15 252:23
275:12,22	29:14 33:21,23	269:18 270:1	216:4 219:9	253:5 254:15
276:11 280:20	78:18,19 82:6	270:12 272:2	225:3 226:16	257:18 260:8
282:9	82:10 85:16	273:10,13	228:23 231:8	263:5 270:17
Care 3:10 7:4	92:15 116:19	276:6 286:4	232:22 237:24	273:3 277:19
31:1 319:6	134:25 135:5	314:17 324:6	253:4 271:10	294:23 298:25
careful 225:12	178:16 179:17	325:1,17	294:19,20	305:10,17
315:23	227:25 231:23	326:24 327:5	311:23 320:22	312:22 314:11
carefully 373:4	245:25 248:10	332:7	certainly 25:24	315:9,17 317:5
Caroline 3:12	262:3,5,8,12	caused 181:12	32:20 38:1,7	317:19,21

318:5,8 319:25 323:15 326:9 332:16 336:16 337:19 339:2 339:21 340:17 343:5,7 346:12 351:2 353:10 353:18,24 354:10 366:24 367:22 certainty 37:21 41:3 157:24 173:6,18 185:8 186:16 222:13 259:23,24 CERTIFICA... 372:1 Certified 1:17 1:19,20 372:3 372:4,18,19,20 372:20,21,22 certify 372:4,7 372:11 374:4 cervical 180:9 cetera 170:7 CFR 46:21 47:2 47:25 chair 355:7,13 chance 226:15 327:13 change 36:8 81:11,14,25 82:14 168:16 220:2 221:24 222:8 225:24 256:22 279:19 293:8 316:11 317:14,17 CHANGE/RE... 375:3 changed 109:21 110:10 164:18 164:21 165:9 changes 45:19 81:15 88:9 165:2 220:6 276:12 279:12	301:19 373:10 374:6 changing 53:5 55:12 222:3 chapter 76:9 290:3,19 291:2 characteristic 148:12 characteristics 70:4 71:25 92:11 131:7 132:10 134:20 147:25 148:1 148:19 149:6 209:7 224:20 233:18 characterizati... 198:1,6 203:5 247:24 characterize 37:18 70:14 75:18 119:16 188:10 248:4 characterized 198:5 characterizing 198:4 chart 89:16,21 check 279:4 chemical 220:13 228:8 266:6 281:13 294:8,9 294:11 295:11 295:13 chemical-grade 227:7 chemicals 166:5 166:10,25 167:8 281:6 290:22 292:25 294:2,19 336:21 337:2 338:10,12,16 346:6 Chemistry 247:9 351:12 children 178:6	178:22 297:1 Chinese 136:23 choose 20:18 119:25 choosing 130:24 202:24 chose 46:11 106:10 118:13 chosen 174:1 Chris 6:24 CHRISTOPH... 2:13 chromium 224:15 263:18 267:1 268:1 271:17 276:17 278:25 312:4 313:10 chronic 72:20 126:6 128:12 179:15,22,23 186:25 187:17 189:20 190:4 190:12 191:1 192:13 196:7 198:25 199:16 199:19,21 200:14 219:25 220:5,22 222:23 227:19 305:12,13 307:4,10,11,12 chronological 14:5 chronologically 62:10 chrysotile 253:24 254:23 254:25 255:5 309:24 ciliary 180:10 CIR 31:10 49:20 57:8,22 65:10 65:23 66:2,6 66:12,22 67:7 67:14 95:4,17 95:25 96:21	97:13 99:14 100:4 120:3,10 120:24 121:21 122:3,3 210:18 245:4 336:7,12 336:15,20 337:1,5 339:16 340:3,5,10,19 341:9 342:2,21 343:11,18 344:2 345:18 345:25 346:7 346:15 347:5 347:10 349:4,4 353:6 355:14 356:8 circumstance 98:18 231:20 circumstances 91:11 97:5 155:14 231:17 231:19 citation 27:16 66:13,15 67:21 99:1 cite 33:14 48:16 48:25 65:21 68:24 76:6,6 76:16,17 85:23 118:13 123:20 126:20 133:4 141:21 142:20 212:11 241:14 250:6 266:16 266:16 274:17 274:23 285:12 285:13 289:20 290:3,6,14 295:20,21 313:18 336:12 336:20 338:21 339:20 cited 12:14 15:19 16:1,9 17:3 20:23 21:23 22:2 33:15,18 54:22	63:11,18 64:8 64:13 66:12 68:16,17,19 77:19 82:25 90:19 118:18 120:18 121:18 176:19 177:11 206:19 212:14 276:2 280:15 292:22 315:8 315:10 cites 339:16 citing 66:19 69:12,16 73:1 139:14 141:23 242:10 243:20 277:3 290:15 290:16 338:2 339:2 349:17 365:14 366:18 citizens 359:20 361:19,21 362:10 363:2 363:10,14 364:25 claim 188:11 222:18 claimed 96:19 claiming 223:18 253:8 344:21 claims 222:20 clarify 63:24 classification 271:17 280:9 classified 197:2 269:5 288:1 classify 309:12 classifying 208:15 215:16 clause 47:15 50:1,9 clear 78:25 87:3 239:20 256:25 262:16 323:11 cleared 311:19 Cleveland 354:16,19
---	---	--	--	--

client 52:8	306:6	50:8 56:18,25	129:3	24:17 40:25
clients 44:6	coming 84:22	57:12,17 58:5	component	96:5 97:4,6
214:1 312:18	179:6 343:13	59:8 123:3,8	127:19 132:2	98:20 170:2
334:9 346:2	commencement	123:13 136:19	149:21 169:12	189:7 198:11
clinical 238:11	372:4	144:11 158:8	171:15	198:19 212:5
clipboard 26:13	commencing	161:8 165:1	components	212:17 221:2
close 368:3	1:15	166:21 167:25	132:2 146:17	241:12 258:14
co-occur 225:14	comment 48:18	177:12 244:3	152:13 163:1	305:25 320:3
coating 175:15	242:3 243:15	318:1 321:14	164:17 166:4	320:10
cobalt 221:14	271:5 341:2,6	324:9 325:12	167:19 168:8	conclusions 41:7
224:15 226:20	360:11 368:6	325:19 326:4	169:6,18,25	85:8 95:25
267:1 268:1	comments 27:17	328:5,23 330:5	170:6 171:3	97:12,14 98:4
276:17 278:25	341:16,19	334:11 352:1	174:19 190:1	98:21 99:11,15
280:3 312:4	342:21 343:7	compare 144:4	205:16 222:8	99:16 119:22
313:10	343:17,22,25	156:18 176:21	224:5 226:10	138:12 140:1
cohort 113:3	345:17 363:15	compared 33:5	227:2,10	141:19 152:11
cold 301:9,18	Commerce 2:5	164:4 204:11	228:19 247:25	168:17,18
collect 312:17	commercially	229:9 231:4	248:5 293:24	202:16 230:1
329:16	251:4	comparison	310:11	233:1 234:9
collected 70:14	commission	161:25 176:11	compound	240:20 319:22
77:9 226:2	374:17	176:16,18	39:13 269:17	320:17,18
239:10,11	committee	177:13 266:13	compounds 34:6	339:1
241:6 257:17	340:6,10,14	comparisons	189:21 225:5	concordance
258:9 260:13	355:9	348:5	270:11 272:17	271:4
260:15 270:4	common 48:2	compilation	273:22 275:16	conditions 39:12
271:8 273:1	115:3 140:12	61:10	277:8 279:12	conducted 58:5
296:8 300:17	199:23 213:23	complete 28:14	338:17	181:18 244:2
328:13	254:2	59:6 73:2	comprehensive	246:20
collecting 229:7	commonly	170:12 270:11	328:9	confidence 40:7
collection 202:8	313:5	320:1	computer 26:19	230:1 370:12
211:7 212:7	communicatio...	completed 91:22	56:9,13	CONFIDENT...
combination	23:17	93:15 201:9	concentration	1:9
168:22	community	completely	295:4 347:18	confirm 14:9,17
combine 65:20	98:14 106:23	163:3 179:8	concept 280:19	14:24 74:13
combined	114:15 115:2	completing 23:8	283:17 289:5	106:6 181:18
201:20 202:1	182:9 183:1	complex 125:17	290:20	288:6,11
come 17:14	190:11,25	146:12,17	concern 223:14	361:16 362:22
58:16 85:8	192:15	151:24 152:2	concerned 52:21	362:24 365:17
98:19 99:10	companies 31:3	153:7 167:8	concerns 48:10	366:4,23
117:6 121:13	31:22 32:1	168:21 169:15	323:21	conflict 349:21
146:15 193:12	43:13 46:3	225:7 226:3,9	conclude 241:17	350:7,9 351:2
219:19 320:2,9	51:5	226:22 256:2	concluded 196:5	352:3,3
335:8	company 30:9	256:15,16	239:20 322:3	conflicts 247:11
comes 123:12	30:23 43:4,15	257:3,9	371:3	349:5 353:7
197:11 285:14	44:1,16,19,23	compliance 44:1	concludes	confused 333:11
301:22 328:5	45:9,15,22,23	44:24 46:11	370:25	338:1
comfortable	46:4,9,11,12	complicated	conclusion	confusion 64:9

252:10	145:9 152:23	consultants	contend 100:4	74:15 75:3,12
connected	153:3 156:4	361:10 362:16	121:1 169:9	78:13 79:8
333:11	159:15 173:12	consulting 336:2	content 26:24	80:11 84:2,6
connection	191:12 194:20	consumer 35:12	contents 262:19	84:10 85:24
10:17,23 108:8	221:10	125:20 126:13	context 93:22	86:5 87:7
consensus	consistent 49:16	126:23 127:9	115:19 205:23	91:23 93:16
181:11 190:10	49:18,19 79:14	127:17 129:4	207:20 213:6,8	95:6,13 96:1
190:24 191:10	88:10 90:22	129:13,15	213:11,25	96:21 105:22
191:17,19	119:9 130:2	131:15 132:4	216:22 218:20	107:9,13 108:3
192:16,25	172:25 187:6	132:11,22	221:9 271:7	108:9 109:10
193:7,15	190:2 191:17	137:9 142:21	307:6 308:19	113:18 118:15
consider 24:11	191:19,24	144:5 153:20	context-specific	118:25 119:6
27:6 30:2 42:6	192:2,6,8,23	154:5,14	212:19	121:23 124:7
42:20 93:8	193:6 194:8,14	155:23 156:2	continual	124:15 126:14
95:7 96:6 97:1	196:16 200:17	157:19 158:15	299:20	126:24 133:12
97:7,7,19	209:15 217:13	159:4 161:13	contribute	134:7 136:2
100:14 115:16	218:17 305:15	164:20 172:15	104:3	142:13,17,18
115:22 122:23	323:25 338:22	175:5,21	contributes	142:22 144:23
132:25 135:6	339:3,13	176:14,23	104:8,12	152:5,15 159:6
151:7 155:4	consistently	178:3,11 180:6	control 209:16	161:5 164:10
167:4 209:19	41:12	226:12 317:25	209:17	164:12 166:8
234:14 246:24	constituent	consumers	controls 83:13	170:9 171:4,19
247:17,21	150:1 152:4,12	30:11 167:13	218:4	173:21 174:8
248:2,19,21	152:14 163:1	327:16 328:25	conversation	175:6 178:18
252:22 255:7	164:17 167:18	330:25	168:7	179:11 180:15
313:22 334:18	169:6 170:6	contact 187:16	convince 82:3	180:24 192:17
334:21	174:19 222:8	231:13 264:17	copies 14:2 18:8	195:5 196:22
consideration	224:3 226:6,7	274:8,8 295:18	copper 117:11	197:4,6 201:10
38:24 39:1	227:1 247:25	296:23 297:3	117:11,14,16	204:19 205:18
288:23,25	262:10	299:3	117:25 217:3	207:6 213:3
considerations	constituents	contacts 264:25	226:19	219:2 221:3
36:24 87:16	29:22,25	contain 10:15	copy 13:21	225:24 227:2
114:21 224:10	127:15 164:3	13:23 59:6	16:11,20 111:7	228:16 233:5
considered	164:20 169:18	145:18,21	111:10	234:22 236:15
35:18 87:5	189:22 221:9	256:21 277:23	cornstarch	238:13 244:5
89:5,17 96:20	225:15,22	contained 9:15	72:18 266:1,10	251:1,17 261:9
107:11 120:17	256:16 263:16	10:13 33:7	correct 10:11	262:4 263:6
120:25 167:12	273:2 274:16	66:10 75:17	14:19 15:1	264:9 269:7
177:2 241:14	274:23 275:10	122:18 209:22	19:16 20:5	270:13 276:6
305:9 311:22	276:10 277:11	251:7 369:17	22:16,22 23:10	278:15 279:13
355:14	277:14,23,25	369:17	34:14 35:1	282:2,20
considering	278:15,18	containing	43:5,22,23	283:18,23
48:9 124:5	289:15 369:10	197:2 225:13	46:13 47:12,20	284:17 287:21
165:22 325:1	369:16,19	contains 74:25	47:21 51:22	288:23 289:18
346:5	370:9	93:13 166:10	59:9 60:23,24	290:9 291:8
consistency 41:9	consultant	contamination	63:6 67:22	292:18 293:13
87:25 119:18	45:22 344:25	249:16	69:19,22 73:16	296:16 298:3

307:22 308:5 308:14 318:22 321:2,9,19 322:19 329:10 330:1 331:6 332:8 336:13 337:8 340:6,7 340:10,20 341:21 342:5 343:12,19,23 348:22 349:6 356:11 359:17 359:19,24 360:4,12 361:5 361:10,15,25 363:14,19 367:3 374:5 correction 245:24 corrections 373:4,7 374:6 correctly 63:3 112:25 113:1,5 204:14 212:24 236:14 289:22 correspondence 27:13 cosmetic 43:9,11 44:11 46:10 47:3 133:11 134:14 135:11 140:18,25 142:2,3,13,15 142:20 145:20 150:25 161:20 162:25 164:8 184:12,19 185:17 187:17 188:12,25 189:17 190:11 190:25 197:2 202:11 203:5 204:16 232:19 233:2 308:12 309:5 322:18 322:18 324:4 324:10 336:6	336:13 339:17 344:25 346:21 347:1 359:23 360:4,7,19 cosmetic-grade 135:14 138:17 cosmetics 30:7 43:12 44:2,25 46:17 161:16 328:3 335:10 336:22 366:11 cosmetics' 346:19 cosponsor 361:4 Council 3:10 7:4 31:2 247:10 319:6 351:12 counsel 2:19,24 3:5,10,15 6:16 122:10 287:11 322:12,13 346:8 372:12 372:13 counted 339:23 couple 100:9 269:22 287:23 290:6 319:7 320:12 370:1 course 204:24 250:7 299:2 369:9 court 1:1,20 6:12 7:17 39:19 137:20 213:16 372:20 372:22 373:19 courtroom 286:25 cover 31:11 70:2 362:1 363:18 363:20,21,22 covered 32:9 61:24,25 74:12 covering 59:21 Cralley 250:5 337:8,17,18 339:16	Cralley's 338:11 338:21 339:9 Cramer 342:20 343:1,3 365:6 crappy 232:2 CRE 362:2,3 367:15,23 create 276:12 306:8 criteria 212:21 critical 236:8 295:12 criticism 353:11 criticisms 348:25 349:1,3 criticize 88:7 criticized 84:1,9 348:20 352:20 353:4 criticizing 353:5 353:6 critiqued 365:5 cross 56:1 180:11 CROSS-EXA... 369:4 crosses 40:7 CROW 2:2 CTFA 31:2 361:4 ctisi@levinla... 2:13 current 5:1 202:7 211:12 currently 44:7 customers 318:21 CV 354:21,25 355:5,11 <hr/> D <hr/> D 3:19 337:12 DABT 1:13 4:13 4:15,17 7:20 372:5 374:12 daily 178:10 187:5 199:22	200:15 296:16 301:8 damage 178:21 228:5,23 231:3 data 36:4,5,12 36:14,22,23 37:8,16 38:25 41:6,10 61:17 70:19 76:14 77:5,8 84:19 88:2 92:21 101:9,10 104:16 106:24 107:24 114:2 114:19 115:21 118:9,10 119:17 120:12 124:9 138:5 140:9,11 145:7 145:7 151:1 153:19,19 157:16,17 158:7,13 163:12,13,14 170:5 171:3,7 172:6,8,8,13 172:16,23,23 173:10 174:3 177:3 182:16 182:17 187:24 194:21,22 195:22,22 205:24 209:8,9 216:4,10,14 217:1,5,16 218:11,12,14 218:15 221:18 221:21 223:2 225:1 226:2,14 229:25 230:2,3 230:4,7,10,13 230:13 231:2 231:14,17,18 231:19,20,23 231:24 232:5 237:17 238:16 238:18,20,22	238:22 240:6,6 240:7 251:6 254:18,18 255:2,15 257:17,19 258:8 260:9 265:19 270:3,4 270:7,11 271:6 271:8 272:25 273:15 275:5 276:2,15,18,23 280:1,6 281:20 282:7 289:12 293:21 296:8 297:15,19 299:18 300:17 301:15 302:13 302:23 305:1 306:21 307:1,2 313:23 320:7,9 328:12,14 database 53:16 53:25 55:24 56:2,5,10 57:13,18 58:23 79:19,23 117:11 databases 54:8 58:5 date 1:16 6:6 9:11 111:14,19 260:8 307:9 372:9 373:9 374:12 dated 9:10 14:8 14:15,21 19:14 267:3 372:23 dates 57:7,8 Daubert 8:10 day 80:10 298:3 300:1,15 303:21 369:7,9 374:16 days 122:5 373:15 DC 3:9 deal 52:11 69:21
---	--	--	--	---

125:3 155:23 dealing 49:15 51:5 61:17,19 131:10 156:1 deals 168:20 dealt 54:18 57:13 145:12 271:14 deaths 178:16 178:18 December 1:8 6:6 10:20 11:1 111:17 decide 26:20 42:4 334:25 decided 60:2 decision 45:5 56:15 67:20 decision-maki... 43:21,25 44:23 45:8 284:8 decisions 97:16 205:1 213:10 deemed 373:18 Defendant 2:24 3:5,10 7:24 defendants 248:4 320:16 defense 85:14 247:1,16 248:17 261:6 261:22 320:25 335:23 defenses 228:15 define 39:24 48:19 169:11 199:16 236:22 237:1 238:5 239:5 272:6 300:20 310:21 defined 227:10 231:6 302:4 305:13 307:14 defines 236:18 237:2 defining 236:9 236:11 237:16	237:19,21 definitely 85:10 95:15 153:12 278:18 308:8 323:16 definition 48:2,4 128:20 237:1 253:16,18 264:11 281:21 283:11 definitions 196:15 definitive 195:4 definitively 189:2,5 227:15 227:17 366:2 degree 41:2 157:23 173:18 185:8 186:15 259:23,24 demonstrate 183:14 demonstrated 69:14 220:25 274:24 demonstrating 73:14 departure 117:12 depend 96:14 230:11 299:2 dependent 155:8 226:18 231:21 depending 137:1 150:11 229:6 232:19 296:24 319:23 319:23 depends 96:11 96:12,13 97:9 128:11 152:16 154:22 168:5 170:16 175:7 228:17 229:11 230:12 234:25 236:21 264:19	269:21,21,22 269:24 296:20 297:5,6 320:4 334:23 335:5 deponent 6:14 374:1 deposed 261:21 deposes 7:23 deposing 373:14 deposit 184:22 deposited 184:13 185:20 296:10,15 297:16 deposition 1:12 4:11 5:3 6:8 8:9,17 9:8,10 9:16 10:4,8,9 10:14 11:4,6 11:13,15,21 12:2,3,5 13:1 14:6,11,14,25 15:6,6,9 16:22 17:13,17 19:24 20:4 22:18 35:10 111:9 112:5 122:5 206:15 211:18 211:21 216:2 251:19,23 252:3,6 261:23 263:23 266:22 280:12 365:15 366:18 371:1,3 373:3,12,16,17 depositions 18:8 92:15 94:2 108:19 136:18 365:18 deps@golkow... 1:22 dermal 233:12 dermatology 352:25 353:14 354:7,13 355:8 Dermatopath... 355:3	describe 28:12 28:13 29:16 37:24 43:11 47:23 77:14 86:9 91:16 101:16 102:7 103:2 104:14 105:10 112:15 117:5 135:1,21 144:17 148:6 148:18 149:5 185:3 189:19 196:11,15 249:2 253:19 289:2 334:2 described 21:24 31:15 45:10 48:8 49:17 51:13 56:25 58:16 79:3 103:23 104:6 104:11 130:12 143:11,12,14 145:3 148:5 152:19 164:25 196:10 219:6 219:15 242:20 245:16 266:15 329:8 330:4 342:15 352:5 describes 141:15 describing 49:19 83:22 87:22 119:23 120:13 133:17 142:3 184:4 249:3 description 4:10 74:25 135:4 199:23 214:21 306:20 331:24 descriptions 89:24 90:18 102:6 156:3 311:2 design 182:2,19	223:24 224:6 224:11 241:2 291:20 297:23 designed 42:15 209:15 230:17 232:2,8 239:5 239:15 240:18 291:8 desirable 132:11 detail 9:18 66:23 70:3 90:9 93:13 94:3 128:5 166:4 214:2 detailed 215:7 details 93:22 109:25 120:21 132:7 208:12 222:1 345:6 detect 42:19 detectable 310:14 detected 170:24 258:16 310:6 detecting 310:25 detection 151:1 151:3 250:9 258:21 310:15 determine 38:15 162:5 163:8 223:8 determines 294:9 determining 36:5 86:18 develop 176:2 179:10 194:15 210:6 220:13 227:14,15,17 230:24 developed 182:12 developing 269:1 273:22 development 24:24 221:22 237:15 238:12
--	---	---	--	---

240:14 272:13 274:1 dialog 213:20 diapering 177:15 dictates 295:11 die 178:23 differ 233:13 difference 67:2 72:17,21,24 146:9 168:17 235:4 314:1 326:13 348:6,7 differences 71:9 71:14 72:5 79:15 82:25 84:16 101:11 101:18 103:11 148:24 156:14 164:24 216:13 225:4 233:3 234:1,7 254:14 265:20,21 266:8,14,17 357:17 different 20:21 22:10 29:7,8,9 29:25 30:16,18 30:23 31:6,8 32:11 34:5,20 35:5,21,23 37:5,20 38:1,9 38:10 39:1 45:24 46:7 50:14 55:19 57:5,5 58:24 62:24 66:21,21 70:20 71:7 75:25 76:13,20 78:7 81:18 83:25 84:13,14 84:23 85:3,5,6 85:8,23 87:15 90:10,10 99:10 99:11 114:8 115:25 119:22 120:5,12 123:7	123:9 125:2,3 126:1 133:9 136:8,24,25 137:5,6 139:5 139:13,22,24 140:9,11 142:13,16 146:5 152:12 152:24 156:15 161:12,21 162:24 174:18 174:19 175:16 177:20 178:8 179:8,16 189:13 198:15 199:4,5 204:22 208:25 213:15 213:18 215:16 215:17,19,20 218:22 219:14 219:16 224:3 224:21 226:25 226:25 227:1,2 228:25 229:1,3 230:23 231:22 233:7,16 234:8 234:10 237:25 244:18 252:24 252:25 253:19 253:22 254:9 254:12 256:12 261:2 265:3 266:4 267:18 269:6 270:18 272:12,15 275:10 277:14 283:2,8 290:7 290:12,22 296:9 305:19 306:11 311:20 320:3,9 322:7 325:18,22 326:6,8,19 328:1,2 329:9 329:14 330:14 330:16,17 332:23 335:21	341:22,23 342:17,17 348:18 357:9 357:14 368:6 369:10,15 differentiate 165:13 differently 37:9 41:22 81:24 84:20 85:12 229:6 difficult 182:18 186:3 222:12 224:7 225:9 291:20 298:1 dig 67:3 Diplomate 1:17 372:3,18 direct 8:1 46:23 76:3 212:4 274:8 281:1,7 281:16 287:11 297:3 directed 53:10 54:10 74:6 162:4 163:8 357:16 directions 329:1 directly 43:17 59:20 76:8 273:9 367:14 disagree 73:25 85:16,17 120:2 127:2 143:22 199:7 214:19 215:13 238:21 241:11,20 283:25 319:17 319:22 320:16 320:25 324:8 339:8,11 342:7 350:2,6,8 356:15,18 disagreed 321:19 disagreeing 343:8	disagreement 321:8 disclose 247:11 350:9,11 353:7 365:6,20 discount 246:14 247:4,5,13 discounted 244:25 discouraging 282:25 284:15 discovery 21:12 54:18 discuss 67:15,18 83:17 98:6 100:6 102:22 103:1 104:25 113:9,13 118:14 119:13 121:21 124:13 126:4 132:23 133:8 140:22 146:10 178:14 187:9 189:12 191:20 192:1 211:3 220:4 242:7 248:25 263:6 277:5 280:17 285:1 289:16 290:8 290:19 355:22 360:22 362:24 discussed 17:19 22:9 35:9 42:17 54:8 65:4 67:10 77:10 91:4 108:18 138:20 148:10 149:20 152:25 154:2 171:17 176:19 181:15 216:1 221:12 223:16 263:23 276:13 277:1 292:19 354:22 362:19 364:6 367:21	discusses 123:17 146:4 193:5 251:20 discussing 54:24 57:1,20 62:14 100:22 104:2 105:8 116:17 120:4 132:15 206:19 276:4 325:11 discussion 66:20 77:25 90:20 102:11,13 103:14,19,22 138:24 147:13 148:16 162:11 180:24 195:8 195:11 214:24 215:3 221:17 223:5 265:7 269:13 274:21 277:2 285:21 325:9 discussions 26:23 89:25 154:9 326:12 disease 38:15 195:5 disreputable 354:7 disseminated 30:22 244:16 244:16 dissemination 123:4,8 distinguish 149:17 distinguishing 148:18 distress 126:7 129:12 distribute 270:2 District 1:1,1 6:12,12 diversity 212:20 dividing 220:8 divorce 332:13
--	---	---	---	---

Confidential - Pursuant to Protective Order

Page 390

334:14	54:15,21 55:14	302:1 304:3	14:22 23:18,20	230:1 232:25
Doc 26:9	55:21,25 56:18	324:1,16,17	24:11 25:4,15	240:19 305:24
doctor 319:5	56:20,24 58:3	327:20 328:9	34:11,23 44:22	319:23
359:16	58:3,17,21,22	330:11 331:21	46:7 50:17	drawing 138:11
document 1:6	59:1,8 76:17	332:2 334:12	63:25 80:2	141:20 152:11
8:19,23 9:1,7	76:21 77:18	348:5 373:8	87:2 88:20	234:9
16:20,25 17:2	83:3 86:8 91:5	dose 187:8,14	93:11 94:1	drawn 98:4
49:3 51:18,19	108:24 109:6	225:2 230:22	95:3 102:10	168:19
53:20 54:22	118:13 123:16	234:21 235:10	105:17 110:3	draws 97:13
55:5 59:19	129:19 130:1	235:10 237:16	111:11 112:4	202:16
64:4,5,7 66:17	130:10 144:11	237:19,21,22	113:6 117:18	Dreessen 135:21
75:2 77:11,14	148:9 154:10	237:25 238:1,3	139:8 140:21	drew 99:16
79:1 80:16	161:6,8 164:25	238:5,9,24	162:7,9 163:4	drilling 193:19
81:9 83:17	165:1 201:12	239:1,2,5,16	163:19 167:24	driven 116:15
90:22 91:19	201:20 202:1,9	239:21 240:10	177:15 201:3	241:1 313:3
92:3,5 111:11	204:12 205:4	240:13,20,23	211:22 236:24	driving 225:23
113:14 170:17	211:7 212:7,13	242:4,14,21	247:24 248:18	Drs 244:11
177:11 201:17	221:11 246:7	243:2,16	248:22 249:3,6	361:14,24
202:3,4 206:14	246:12 248:8	254:14 259:4	251:15 252:2,5	362:15 363:23
211:10,19,22	248:12 249:1,4	259:25 260:22	252:11 259:17	364:3 365:23
212:6,16 245:5	250:8 252:21	263:18,25	261:7,18	drug 355:7
251:22 282:24	253:19 259:16	281:25 282:18	262:20 287:8	drugs 189:22
290:17 292:22	284:9 288:15	282:21 284:14	287:16 314:4	Duces 4:12
292:23 341:23	309:11 321:10	286:3 293:25	337:8,17,18	due 128:17
342:19 364:2	321:13,14	294:8,22	338:11,21	291:18
364:22 365:2	323:24 341:7	295:11 302:19	339:9,16	duly 7:21 372:5
365:13 368:9	342:17 348:17	dose-response	342:20 343:1,3	duration 239:10
368:13,18	350:10 354:24	224:14 235:13	349:9 352:20	302:19 305:12
documentation	362:13 364:5	235:19,24	354:14 355:13	dust 15:16
10:6 48:18	366:3,7 367:20	236:11,18	357:1 361:8,8	duties 329:14
82:16 212:22	368:13	237:2,6 241:16	364:23 365:4,5	duty 318:14
214:9,14	doing 33:25 34:7	241:18 293:23	365:6,15,19,22	325:12,19,19
218:22 278:11	38:4 53:15	294:12 295:17	369:6,8 370:18	326:3 327:3,4
documenting	74:10 79:11	doses 231:5	draft 20:19	329:14,15,21
249:21 273:9	94:8 115:5,24	242:19 295:3,4	74:21 201:14	330:5 331:16
274:18	116:3,5 119:14	doubt 230:14	202:3 205:11	332:16
documents 9:23	123:3 130:13	242:3 312:20	341:23 342:1	DYKEMA 3:1
10:13 12:13,14	155:21 157:10	doubts 230:14	343:18,25	
15:11,19,22,25	169:14 171:24	Doull 289:21	345:22	E
17:15,21 20:22	181:25 205:1	290:4,5,18	drafted 32:20	E 2:1,1 3:1,19
21:3,6,10,18	208:3 214:1	download	46:16,18	3:19
21:20 22:13	216:3 217:13	123:19 345:9	343:23	earlier 9:2 20:2
27:4 29:1	218:13 234:23	345:13,15	drafting 23:12	62:13 63:3
30:24 32:12,18	234:24 244:23	dozens 97:25	24:2 26:1 66:1	68:17 74:12
33:15,17 51:12	287:11 291:14	Dr 6:14 8:4	68:10 80:19	104:18 205:13
52:1 53:12,21	293:8 296:20	12:23 13:20	draw 41:6 140:1	237:8 265:1,22
53:22,25 54:7	301:3,4,10	14:7,10,15,17	168:17 170:2	297:14 298:10

305:13 317:7 330:21 early 20:12 23:3 80:20 179:6 285:13 easily 72:8 East 3:3 easy 62:7 Eberl 15:21 Edelstam 68:4 69:2 70:23 73:14,20 editor 27:9,13 27:17 effect 34:3 140:20 145:20 235:24 240:25 278:3 282:1 289:10,19 291:6 293:2 294:10 Effectiveness 367:3 effects 29:24 77:9 124:14 132:1 139:4 146:19 153:3 156:4 169:25 190:3 224:5,14 236:13 242:5 242:16 243:13 290:21 292:13 292:14,17 294:2 295:2 effort 348:6 Egli 16:6 eight 11:10,17 96:20 97:24 98:2,5 100:2,5 100:13,25 102:5 104:18 104:22 120:25 121:20 183:23 either 9:2 31:16 36:6 41:7 51:17 55:5 61:18 82:17	114:19 132:21 136:22 191:4 202:24 224:2 244:3 245:14 269:6 273:6,8 274:12 290:12 292:6,16 302:3 326:25 347:18 353:11 elements 152:4 152:15 310:5 elicit 23:22 eliminate 312:25 ELLIS 2:21 3:12 else's 357:18 emphasis 47:10 emphasize 47:19 employed 75:16 employee 45:21 365:16 366:18 372:11,13 employees 136:19 enable 26:6 enables 273:11 encompassing 108:22 encounter 335:22 ended 136:1,7 141:1 ends 31:15 80:21 131:14 132:3 England 27:10 English 48:2 engulf 150:18,18 engulfed 125:7 ensure 130:17 entire 43:10 105:2 171:14 171:19 entirely 179:16 284:16	entirety 57:25 entitled 206:23 211:10 entity 147:23 environment 103:15 229:2 306:8,12 environmental 105:5 EPA 65:10,22 213:13 243:20 243:21 290:14 290:16 292:22 292:23 epi 42:14,21 106:24 173:10 173:13 208:4 epidemiological 41:20 79:9 106:23 114:2,6 114:19 115:16 116:1 172:7,8 205:17 239:14 312:11 357:7 357:23 epidemiologist 41:16 84:20 85:1 356:3,7 357:24 epidemiology 37:11 38:25 81:17,18 89:11 106:4 115:2 295:10 355:22 355:24 356:21 epithelial 233:19 equal 232:12 248:6 errata 373:6,9 373:11,14 374:7 375:1 escape 180:12 especially 61:16 212:23 274:7 297:24 312:23 essentially 12:12	77:3,21 116:11 154:10 202:17 217:14 222:16 328:21 331:23 establish 185:17 275:15 established 189:3 195:4 establishes 71:1 et 4:20 170:7 ethicality 182:23 ethicist 352:8,11 352:17 ethics 73:22 187:22 evaluate 37:8 104:15 271:25 evaluated 32:17 37:8 66:5 evaluating 40:11 44:1,24 96:8 127:16 137:4 205:17 225:21 246:19 252:14 evaluation 27:2 65:25 105:7 169:22 174:2 192:12 196:20 245:18 289:1 304:10 357:6 evaluations 244:17 evening 12:9 event 184:5 281:9 367:24 events 128:2 194:18 220:16 294:14,16 367:25 eventually 80:22 81:9 everybody 228:7 evidence 5:1 21:14 37:11	38:8,14 39:5 42:5,24 67:2 70:9 73:21 75:24 76:10 77:13,17,20 78:3,10,13 80:6 81:6,13 83:7 84:13 85:23 86:10,23 87:4,6,14 88:5 88:18 89:4,6 89:16 90:5,11 90:19 96:7 97:2,19 98:24 103:5 104:3 105:11,16 107:2 112:15 112:17,21 113:16,17 114:12 115:16 116:1,10,15 117:8 120:19 135:7 139:23 139:25 143:19 155:2 159:11 172:9,21 173:2 173:9 174:16 176:16,17,20 177:2 192:22 194:9,10 197:23 198:13 199:9 205:16 208:25 209:10 210:1,9,25 211:10,11 213:2 214:15 215:4,24 218:23,24 222:23 223:17 229:5,5,19 236:8 240:4 244:14,20,24 245:1,6,18,23 246:14 248:23 249:15 250:7 252:13 254:19 257:15 260:16
--	--	--	--	---

Confidential - Pursuant to Protective Order

Page 392

261:4 285:22	78:12 79:5	exercise 86:11	265:20,22,24	261:20 320:16
288:20 296:18	80:10 82:2	120:6 216:16	274:13 302:14	320:23,25
326:2 327:12	83:24 86:20,24	216:20,24	expected 175:9	335:22
339:3 365:25	87:11 88:3	219:14,17	289:9	expires 374:17
366:22 367:1,4	89:16 97:23	326:20,22	experience	explain 35:7,22
367:14 368:1	101:8 102:20	exercises 218:8	37:18 39:6	41:13 49:2
369:20	114:10 117:3	327:1	44:4 46:10	93:21 100:11
evidence-based	123:16 125:5	exerted 31:22	48:7 49:14	120:6 121:7
295:10	133:5 134:14	exhibit 8:13,18	50:3,23,25	135:18 174:15
Eviron 346:15	135:5,8,20	9:8 14:6,11,14	51:5,22 77:23	235:2,3
346:25	142:22 143:2	14:18,20,25	84:23 105:13	explains 133:22
evolved 109:21	148:5 149:16	15:7 16:16,22	115:11 116:5	explanation
exact 65:18,19	151:8,18	17:9,14 19:23	207:25 264:5	59:7 195:3
110:16 167:17	155:15 163:15	20:4 22:21	271:7 320:8	explore 94:6
193:12 203:2	163:21 165:4	23:9,13 24:13	334:7 336:3	exploring 285:3
321:23 339:20	167:20 173:19	25:19 26:25	344:5	expose 224:2
exactly 47:13	175:8,12 177:3	28:5 29:2	experiencing	291:21
67:24 69:24	192:24,25	46:24 53:6	99:8	exposed 156:10
73:10 82:5	196:5 204:6	64:3,19 65:14	experiment	176:24 187:15
89:14 134:18	216:9 221:15	66:11 75:3,12	223:25 224:1	220:12,12
168:11 178:25	222:19,22	75:18 76:5	291:7,14 293:9	226:8 228:8
190:16,20	229:10 232:23	90:8 93:16	293:12	237:14 258:11
204:6 205:3	233:19,24	95:11 111:4,9	experiments	259:5,25
209:3 221:7	237:13 239:7	111:13 112:5	181:18 293:21	263:19 286:10
223:8 224:21	240:7,16	113:12 155:14	expert 4:11,13	290:22 291:23
224:22 249:2	242:24 246:3	201:10 202:15	4:14,16 12:25	301:17 335:14
253:19 303:4	247:23 263:19	206:16 209:23	13:5 14:7,15	exposure 16:4
304:19 320:20	270:5,9 271:11	210:22 211:14	14:21 15:5	36:8 37:2,16
examination 8:1	271:13 281:17	211:18,21	20:19 23:8	39:11 41:3
287:14 319:3	285:12 286:2	219:16 266:22	24:24 130:22	52:23,24 76:14
372:5	292:9 296:21	Exhibits 4:9 5:3	137:3 139:11	77:6 78:7 81:1
EXAMINATI...	296:25 299:5	13:17 28:1,4	148:23 213:16	112:12,21,23
4:4	311:6 312:24	33:7 57:24	246:21 247:1,1	117:15 132:23
examine 161:11	314:22 322:3	exist 43:10	248:17 255:8	133:16 160:19
161:20	334:1 335:1,23	150:20 268:22	255:20 261:12	174:20 175:3
examined 207:9	336:21 342:12	existed 318:20	261:22 262:20	175:11,20,23
examines 266:8	361:3	existence 346:15	334:19 342:4	175:25 176:12
examining	examples	exists 151:12	344:12,15	176:21 177:14
295:12	245:10	169:20 200:8	346:19,24	177:16 178:3,5
example 27:3	exception 81:16	226:23 228:15	347:2 349:5	178:10,11
36:16,19 37:9	172:7 178:4	261:5 306:25	expertise 255:13	179:21,22,24
38:16 40:16	296:1	exit 180:22	269:17 355:19	194:12,16,22
51:21 56:23	exclusively	expanded	357:22 358:6	195:19 198:20
58:19 59:18	54:13 176:3	331:18	experts 29:8	198:21 199:12
60:13 61:16	excrete 313:5	expect 72:8,20	85:14 148:17	199:20 200:13
62:12 70:24	excuse 214:18	73:7,10 178:1	181:16 248:3	202:21 203:1
72:7 76:22	275:22	233:21 261:24	248:15 261:6	203:21 204:2

217:11 218:11	extrapolation	factors 112:14	FDA 43:12 44:1	365:20
218:12 220:15	232:13 270:5	156:15	44:24 47:23	financially
226:11,12	extremely 50:10	factory 175:15	74:4 244:17	372:13
230:20 231:11	80:15 97:19	fail 373:17	328:19,19	find 57:18 78:4
233:12 235:8	99:18 100:10	failed 95:17	336:17 340:4,5	84:8 133:6
236:10,12,19	100:14 138:18	355:18 365:6	340:14 359:22	146:3,6 155:25
237:3 238:25	231:14	failing 97:7	360:2,18 361:3	177:7 209:23
242:16 243:17		353:6 365:20	361:7,15	210:20 222:5
243:19 257:16	F	fails 96:6	FDA's 332:5	246:1 249:18
258:3,5,10	F 3:8	failure 97:1,18	355:7,7	262:21 269:13
262:7,9,11	face 250:25	fair 23:6 60:19	feel 121:8	276:18,22
269:25 272:22	251:2,16 284:9	122:17 199:25	129:14 306:6	280:16 292:13
274:15 285:10	319:9	199:25 231:16	feels 94:16	364:6
286:4 291:19	fact 12:24 15:3	299:24 304:18	felt 59:19	finding 41:8
292:4 294:9	32:1 34:17	fairly 128:19	female 103:11	42:10,13 55:25
296:6 297:10	62:14 66:24	231:9	183:16 184:3	findings 67:19
299:19,21	67:15 75:7	fall 23:3	295:24	91:3 172:25
300:8 301:12	79:1 88:6	fallopian 4:23	fiber 147:22	fine 14:3 275:5
301:24 305:12	91:18 100:18	103:16 180:11	150:5,6 255:3	313:16 336:10
305:14 306:13	108:2,6 125:17	180:22 181:8	258:18	364:14
307:4,11 313:4	128:17 129:2,3	181:13 183:17	fibers 251:8,9	finer 129:14
322:4,15	134:23,25	falls 295:5	256:7 258:16	fines 130:20
324:22 329:6	136:10 150:23	familiar 107:8	259:1	131:3,5
347:19 370:14	151:24 167:25	107:22 118:24	fibrous 124:23	fingerprint
exposure-resp...	168:20 177:20	123:21 130:19	124:24 126:1	145:5
230:15	179:3 197:1	131:25 132:7,8	146:9 147:14	finish 94:13
exposures 217:9	205:14 207:17	147:4 166:7	148:24 149:14	finished 44:18
243:4,14	217:3 221:3,17	196:20 205:25	150:14 151:2	127:6 308:12
300:24 301:8	222:13 225:3	211:21 216:15	151:19 161:11	first 7:21 11:5
301:20	230:7 243:13	283:16 313:7	161:22 253:20	15:19 16:14
expressed	252:11 256:1	319:10	255:2,3	19:13,18 28:24
109:23 286:22	257:9 258:20	far 11:10 39:6	figure 103:7	28:25 32:5,17
320:21 323:25	272:13 273:22	66:20 77:5	figures 103:9	32:17 33:16
333:15	281:23 289:4	84:21 88:14	file 80:17	36:1,2 48:1
expressing	292:12 299:17	92:22 107:5	filed 12:7 16:10	52:2 53:9
166:19 316:7	301:16,19	117:7 128:1	18:2 23:4	54:11 56:17
339:13	302:20 321:4	130:23 145:3	files 57:12,12	61:8,11 65:21
expression	321:25 324:9	146:19 149:9	251:24 253:14	87:21 112:19
194:4	332:13 346:9	165:2 167:7	filter 129:8	137:12,18
extent 55:20	348:10 349:15	170:13 171:11	fimbriae 180:12	147:11 198:16
183:8 214:20	370:8	192:4 193:15	final 37:1	210:6 212:6,17
215:13 252:9	factor 36:16	216:8 227:9	138:11 153:11	215:25 217:2
268:22 309:12	88:15 110:18	233:18 238:6	172:14 174:11	248:25 256:25
extra 228:21	111:2 157:9	244:17 268:11	343:23	326:22 327:5
extrapolate	158:3 169:3	272:22 293:22	finalized 316:4	329:15,22
232:16 272:1	171:23 225:23	328:4 336:18	finally 42:4	331:11,12,14
273:11	272:21 295:12	fax 1:22	financial 365:7	331:15 343:18

352:22 354:15 354:18 355:2 359:25 fits 41:11 281:20 281:20 283:11 five 210:17 249:9 flags 13:24 Fletcher 313:20 313:21 314:18 314:19 315:2 Florida 2:14 fluids 72:9 FLW 1:5 focus 58:12 94:5 151:20 153:14 155:22 268:14 270:8 321:16 330:8 363:8 focused 22:18 37:12 58:17 262:11 268:8 370:5 focusing 36:18 56:23 77:12 125:9 129:17 168:7 179:23 204:10 348:10 348:10 folder 26:17 follow 46:12 67:6 117:22 346:4 358:22 follow-up 358:12 followed 113:17 following 25:3 40:8 66:25 345:25 follows 7:25 46:4 food 311:6 footnote 317:8 318:16 336:22 336:24 foregoing 372:8 374:4	foreign 128:19 150:10 forgot 11:16 form 49:10 73:17 75:11 87:8 89:19 90:12 91:24 99:5 105:23 106:13 107:15 116:11,18 118:16 121:3 121:15 126:25 130:7 133:25 137:11 141:2 145:23 147:20 150:14,15 153:4 154:20 157:7 159:7 160:10 162:1 171:5 180:16 185:6 186:11 186:22 187:18 191:6 195:6 198:8 214:18 242:21 252:16 255:6 259:10 261:10 262:24 264:14,19 270:14 283:24 284:18 298:6 300:3 303:8 330:19 337:17 343:25 345:22 351:20 356:10 369:24 374:6 formal 113:17 formation 215:11 276:13 formed 32:19 66:15 125:14 145:24 146:2 151:22,24 166:17 167:10 176:6 181:14 184:15,17,21 184:25 186:24 190:17 191:3	198:13,18 237:5 260:7,9 265:13 274:11 286:6 299:14 303:9,22,25 306:17 307:8 337:24 338:7 338:11 339:10 353:16 354:1,8 355:15,17 358:8 former 355:7 formerly 31:2 forming 53:13 61:7 80:1 85:24 89:17 103:4 324:21 forms 73:20 130:17 148:4,4 253:22 254:3 255:3,4 formulated 300:5 Forrest 10:9,14 forth 75:1 323:10 372:9 found 41:8 91:18 100:10 264:21 311:5 337:5 foundations 161:17 four 1:13 172:5 208:16 271:12 290:23 Fourth 3:13 fragrance 166:4 167:22 168:6,8 169:7 275:10 276:10 278:14 278:17 308:22 337:3 frame 20:13 54:23 framework 204:25 free 26:15	frequency 184:18 185:19 186:10 239:10 302:18 frequent 305:2 frequently 359:22 360:2,6 360:23 366:11 Friday 9:4 front 13:21 206:14 full 34:7 35:15 57:25 119:14 163:12 331:22 fully 282:6 366:8 functions 332:5 fundamental 294:1 funding 350:12 350:13,14 further 65:24 67:4 93:21 141:16 197:19 314:16 368:19 370:17 372:7 372:11 <hr/> G <hr/> G 3:19 gain 226:5 game 122:17 Gardner 68:4 gather 78:3,7 gathering 77:5 293:22 general 5:1 27:23 30:18 33:25 34:25 35:14 75:14 78:15 125:24 126:8 151:6 154:9 192:15 209:16 211:11 265:7 275:19 278:4 291:2 294:4,25 295:2	304:25 308:4 348:25 366:5 generally 29:20 57:2 61:20 64:23 70:10 72:25 77:20 81:23 98:13 101:12 126:9 127:22 130:21 139:15 219:25 222:2 237:6 253:2 282:25 289:7 291:11 291:24 294:24 295:15 297:7 360:24 generate 276:12 279:12 generates 27:4 genetically 292:1 genital 37:3 68:7 69:10,15 70:6 72:1 73:16 110:13 202:25 265:5 295:23 295:25 genotoxic 280:20 281:7,8 281:9,18 genotoxicity 281:15 geologist 149:8 geology 132:15 255:11 GEREL 2:8 getting 31:15 54:2 301:7 327:3 331:13 ghostwritten 246:9 GI 233:24 271:20 give 26:12 34:25 46:2,8 51:21 60:25 80:7 83:8 84:5 85:5
---	---	--	--	--

88:22 92:12	25:7 26:15	131:10 132:14	guarantee	31:6 45:14
93:5 98:4,12	32:6 35:20	135:15 136:14	293:14	46:2 360:14
98:20 101:4,22	36:25 37:5	148:18 167:8	guess 18:20	happens 27:10
102:18 103:20	38:9 45:6	175:23 188:3	30:13 56:22	27:14 82:13
103:24 110:9	49:11 51:11,25	200:21 228:9	101:15,21	85:9,18 291:15
114:5,18 120:3	52:3 55:24	230:3 232:8	143:22 147:24	298:17 302:3
133:23 138:17	56:10 57:18	235:16 241:22	149:11 178:10	342:8
140:23 141:7	61:5 66:24	259:2 287:3	193:9 202:2	happy 370:18
155:6,14	68:20 75:25	300:7,10 328:8	285:14 311:21	hard 193:24
217:19,23	76:11 77:3,15	341:9 343:6,12	323:23 351:10	hazard 36:1,2
229:8,12 230:9	94:20 102:15	345:22 347:24	366:15	37:15 47:6
230:18 244:1	104:15 106:24	349:22,23	guidance 49:3	48:14,14 77:1
248:6 252:13	109:24 120:19	359:1,4,8	49:13 51:12	77:2 82:2,4
255:16 259:22	123:19 130:23	364:14,15	61:1 76:17	143:19 153:9
303:3 314:1,11	141:16 146:7	368:24 369:14	290:17	165:21 167:2
334:9 368:17	152:21 153:13	371:1	guidelines 186:5	168:12,14
given 27:5 60:16	159:13 178:22	Golkow 1:21	guides 335:9	169:12,19
89:23 94:1	188:2 194:11	3:20 6:4	gynecologic	170:23 171:8
99:2 109:5	200:20 219:20	Golomb 2:16,17	359:15	171:10 197:21
121:14 127:14	220:7,19	7:1,1 19:5	gynecological	197:22 204:7
154:16 166:22	221:16 222:3	Gonzales 118:14	182:9,25 356:1	229:21 234:24
174:10 210:24	235:21 245:23	120:1,14,16	356:1 358:3	235:1,5,6,8,11
212:18,19	251:19,25	Gonzalez 118:25	359:12	235:14,15
219:4 226:14	254:24 259:18	good 8:3 58:8		237:23 243:15
230:6 244:25	273:16 274:19	100:17 168:10	H	256:8 268:18
251:20 255:16	276:16 280:4	192:25 201:2,4	H 3:19	285:15 289:6,7
261:22 280:15	280:10,13,14	270:7 287:16	habit 187:5	297:24 314:22
302:7 304:5	280:16 287:22	302:3 369:6	200:13 299:20	326:1,3,6
315:17 351:2	288:21 289:4	Gordon 250:3	299:21 301:21	327:16 332:15
374:5	299:7 312:16	government	307:3,10	334:4 338:18
gives 50:25	321:6,7 323:3	17:4	habits 101:13	370:10
99:15 202:19	330:6 337:19	grabbed 121:25	301:11	hazards 15:15
246:10	338:20 341:8	grade 135:11	Hamilton	178:14 236:10
giving 8:9 46:1	346:3 347:8	140:15,18,18	242:25	322:15,16
83:21 104:4,5	353:25 358:11	142:8	hand 53:1 83:16	323:9 335:11
105:6 107:5	359:4,6,6	great 211:4	handed 8:20 9:7	he'll 26:15
114:11 115:25	364:4,8 366:23	greater 38:14	111:12 211:20	head 52:4
120:9 141:5,6	368:14	125:1 178:2	handing 8:16	health 4:21 5:2
158:1 171:22	goal 36:23	292:16 303:7	111:10	15:15 36:3,20
171:23 203:16	goes 42:23 121:6	303:12,15	handled 122:3	47:6 48:13
219:1,12	192:3 251:25	304:15	handles 122:3	107:3 115:7
306:20 353:10	going 13:7 24:18	group 122:2	Hang 23:14	166:11 178:14
globally 142:16	25:10 40:25	131:6 217:22	happen 69:3	201:6,13,17,25
GLP 88:3 232:3	55:12 80:15	grouped 118:6	97:4 181:6	202:9 204:13
glutathione	81:1,6 85:10	groups 209:17	300:8 343:21	204:24 205:6,9
228:22	94:15,22 99:21	209:17 217:15	361:1	205:23 206:20
go 13:5,13,14	101:24 118:1	218:15 219:6	happened 27:22	211:7,12 212:8

216:3 236:13	29:23	295:19 302:24	283:12 289:6	117:12 141:14
283:21 284:7	history 354:25	305:1 322:14	300:23 301:5	156:7 235:16
284:13 312:16	hold 24:4 267:14	323:9 334:3,16	306:21	366:12
322:15 323:9	294:18 318:4	humans 101:12	identification	ignore 46:13
331:25 334:16	339:6 358:10	101:14,18	8:14 9:13	Illinois 1:18
heard 357:15	holiday 370:19	117:14 182:13	13:18 16:17	372:20
heavily 344:6	honed 79:24	197:3 231:9	17:10 111:5	imagine 46:14
heavy 146:13	honestly 61:24	232:17 270:6,9	206:24 211:15	Imerys 3:5 7:9
169:9 170:7	HONIK 2:16	270:21,24	285:19	7:11 30:25
264:1 266:25	Hope 2:23	279:24 291:22	identified 9:17	58:22 144:16
267:18 268:1,6	hopefully 34:8	Huncharek	17:23 23:12	250:8 287:18
268:8 269:5	315:6	244:11 246:2	24:13 25:24	307:20 308:3
272:3 273:9	hospital 178:22	361:8,14,25	26:25 33:2	308:11,24
274:22 276:10	hot 301:6	362:15 363:23	53:20 54:1	316:15,20
278:14 288:1	Hotel 1:14	364:3,23 365:5	65:10 75:3	317:8,19,24
310:11 311:2,3	hour 19:3	365:23	83:25 113:11	318:2,13,20
311:13 312:17	hours 11:10,18	hundred 166:25	122:11 147:24	367:5 368:4
312:21,22	18:20,21 19:4	hurry 292:2	147:25 148:1	Imerys' 317:22
313:2,9	88:21	husband 25:23	158:16 170:20	immediate
held 1:13 6:8	Houston 26:8	26:4,23 62:15	200:6 212:8	178:20
help 25:23	human 15:15	62:19	236:9 245:13	immediately
236:23	36:3,20 37:18		253:6 288:2,12	178:24
helpful 13:4,12	71:25 96:20	I	309:10 332:15	immune 276:21
84:9 94:3	100:7 101:9,24	IARC 31:12	338:13 362:16	impact 334:11
112:1	104:4 107:3	65:10,22 76:25	identifies 37:14	imperative
helping 151:15	115:7,20 118:6	148:6 149:16	282:17	373:13
helps 111:20	118:9 119:8,17	151:8 191:20	identify 6:16 9:6	importance
hereinbefore	142:2 153:19	192:24 196:4	13:2 15:7 27:5	101:1 104:10
372:9	153:19 157:16	196:20 197:1	55:15,24 59:8	104:23 105:6
high 88:4,16	157:17 158:13	198:5,9,17	68:15 77:1	256:14
235:10 295:3	160:7 172:23	199:5 204:7	95:10 96:19	important 21:1
higher 175:4	172:23 182:16	221:15 232:4	100:3 133:10	30:5 50:10
198:4 229:18	186:5 187:22	254:4,16	139:22,23	81:4 84:25
highlight 80:14	197:5 205:23	271:18 277:3,4	144:15 154:3	93:22 97:20
80:17	216:3,10,25	277:4 280:9,13	156:14 160:6	99:12,18
highlightings	217:7 219:7	287:25 288:10	168:14 224:4	100:10,15,23
13:24 16:25	229:3 230:10	324:24 325:23	225:2 235:11	103:3,6 104:9
highly 314:8	230:13,13,18	348:3,14	237:12 250:12	104:19 105:3
Hill 36:24 38:24	231:4,14,18,19	idea 44:12 46:4	250:23 251:16	122:14 135:15
74:15,17,18,21	231:24 232:2,3	48:8 86:16	266:25 267:17	138:18 141:18
75:2,9 114:20	232:12 238:16	90:23 118:8,9	267:25,25	143:18 150:19
159:14 194:8	239:3,13 240:6	125:22 126:5,7	276:11 282:10	152:3,6,11,13
195:10 196:17	240:17 241:13	149:25 152:20	282:16 294:22	152:22 159:12
hired 364:3,23	256:17 269:7	160:18 166:5	305:21 310:4	167:17 168:3
367:15	270:7 271:6,12	194:2,9 220:13	326:17 332:14	169:8,21
hiring 367:4	271:17 279:25	243:16 246:5	identifying	212:23 215:10
historically	280:1 295:14	256:6 273:21	53:12 61:6	229:16 231:15

234:6,21,25	219:19 237:23	160:12 180:21	induced 279:7	26:5 30:8,12
235:20 242:13	274:25 369:21	226:14 260:10	inducing 281:14	30:21 35:18,21
245:8 256:4	increased 36:11	305:1 306:22	indus 344:19	37:14 39:8,10
260:23 271:6	37:10,23 39:11	indicating 364:2	industrial	41:11 54:4
314:21 357:24	39:17 112:23	364:22	133:12 134:13	70:13 74:3
358:2,6	146:16 156:8	indicative	135:11 140:18	76:15 78:2,4,8
impossibility	157:12,22,25	179:18 238:11	142:8 155:16	79:23 80:14
347:25	158:14 159:17	indirect 281:15	industrial-gra...	82:15 86:18
impossible	160:3 172:2,4	282:11	145:18 227:6	91:1 92:8,11
186:4 207:24	172:10 173:1,3	individual 29:21	industry 31:14	103:3,4,23
224:8 348:13	173:5,12,19	120:12 127:9	124:1 245:19	104:8 106:2
imprecise 283:5	174:7,8 200:4	127:15 152:14	340:23 341:3	118:3 121:14
in-depth 71:14	204:21 229:20	169:17 171:15	344:8,19,22	122:22 123:4,9
71:21 72:4	239:21 274:14	173:8,9 183:22	345:1 350:14	127:15 134:13
inaccurate	286:11 306:18	189:23 200:11	350:15 352:1	135:13,17
67:13	324:22 326:18	221:8 224:4	362:18 365:21	138:13,17,25
incapable	327:21 332:7	225:22 226:10	366:12 368:8	141:15,18
270:13,16	332:20 335:17	239:25 246:6	inert 183:15	143:5 158:24
include 11:12	increases 34:18	259:25 263:19	184:10 185:4	159:3 162:6
60:14 87:13	35:4 38:17	278:20 286:5	inflammation	164:14 165:23
120:1 150:22	39:20 40:13	293:24 305:9	61:19 126:6	165:24 166:20
202:2 210:24	41:4 157:18	322:1,6 334:23	127:24 128:2,9	167:13 168:3
239:9 262:10	198:22 203:22	334:24 350:15	128:13 140:14	170:10,11
273:2 342:3	203:25 237:22	350:15	196:7 219:25	180:20 185:23
347:21 355:18	238:3 286:22	individual's	220:1,15,18,19	191:14 194:14
included 122:1	306:24 319:18	180:7 185:21	220:20 221:1	197:15,18,19
210:1 218:24	321:1 329:25	individually	221:20 227:20	198:17 205:4,9
239:9 338:16	331:5 370:11	100:21 149:7	268:13 276:5	216:12 217:6
includes 86:22	increasing 169:3	154:8 158:25	inflammatory	217:15 218:11
87:15 151:25	independence	171:12 219:21	128:16 168:25	218:12 219:10
198:17 256:16	348:7	234:4 272:8	189:20 190:4	221:1,6,12
274:15	independent	275:8	190:12 191:1	237:11 239:9
including 11:14	51:18 257:8	individuals	191:21 192:13	241:6 247:2,4
29:21 62:18	272:7 325:24	25:18 78:14	220:5,23	247:18,19
71:18 215:5	329:9 337:18	85:11 115:13	222:23 228:1	253:1,1,3,12
219:25 251:5,9	340:4 362:16	121:13 131:9	243:18 266:2,5	253:13 260:12
261:6	independently	159:5 218:9	266:9,11	260:14 284:6
inclusion 218:3	338:10	228:11 239:7	272:14 274:9	293:23 304:5
331:19	INDEX 4:1	241:3 244:2	276:19 277:9	314:8 318:19
inconsistency	indicate 227:13	256:9 286:10	279:2,6,10	323:23 329:16
317:14,17,18	240:24 247:19	305:7 320:6	influence 31:4	331:1,24
inconsistent	254:19 299:18	342:18 349:18	31:22	332:23 334:11
113:4 275:4	307:3 317:8	353:8,12,18,20	influenced 32:1	336:15,17
increase 37:10	327:12	354:2 355:19	influences 123:7	337:1,4 339:12
39:18 40:15,19	indicated 63:3	induce 277:8	information	339:25 342:2
158:4 171:21	250:25	278:23 279:22	10:12 15:15	349:16 359:23
172:1 199:12	indicates 113:2	281:22	17:18,20 23:22	360:3,3,20

368:7 370:3,5 informative 84:10 100:23 101:6 219:10 219:11 221:6 informed 95:18 ingredient 52:21 125:21 132:21 307:25 308:2 309:3 336:6 341:20 342:3 346:21 ingredients 44:10,15,17 125:18 127:10 144:4 168:22 309:14,18,20 322:18 324:4 336:13 337:3 339:18 341:9 344:9 346:19 347:1,5,12 348:2 inhalation 175:4 175:20,24 176:4 177:5,14 177:25 178:2,6 180:3 230:20 233:12 235:9 258:12 291:14 292:6 inhaled 264:21 inhaling 178:7 258:25 inherent 245:22 initial 21:15,16 55:9,11 56:24 64:16 65:25 82:1 231:8 235:6 246:13 281:22 342:3 initially 54:11 55:2,3 329:12 initiate 128:16 initiated 88:11 220:14 initiates 328:6	initiation 281:10 injections 292:8 injury 178:19 231:8 264:22 input 44:8 45:5 45:11 245:15 340:19,23 341:2 insertions 101:14 inside 105:6 296:7 installation 242:20 instance 79:5 230:9 instances 53:10 62:15 84:4,8 184:22 Institute 4:25 107:9,17 108:6 110:6,24 112:6 113:10 instruct 24:18 instructing 24:22,25 instructions 25:4 373:1 insult 225:3 281:1,8 insults 195:25 intact 229:1,2,3 intend 203:15 intended 23:22 intending 33:24 34:11 43:3 intention 130:4 interact 264:15 277:15 interaction 276:21 277:20 360:14 367:23 368:4 interactions 31:3,13 interchangeably 75:23	interest 349:5 349:22 350:7 351:3 352:4 353:7 interested 88:22 94:8 249:12 372:13 interesting 121:25 140:10 178:13 297:22 interim 231:1 internal 30:23 144:11 246:12 321:14 internally 67:9 67:16 297:10 326:7 International 346:10 interpret 230:3 interpretation 49:7 50:1 51:1 255:14 interpreted 50:11 interpreting 50:18 51:19 interrupt 359:2 359:9 interrupting 358:15 interruptions 136:24 interval 40:7 intimately 334:15 intraperitoneal 292:8 introduced 8:4 introductory 124:17 invented 115:14 investigate 353:3 investigations 239:14 investigator	246:6 investment 244:4 involve 24:23 154:14 214:2 258:5 295:24 involved 11:3 23:11 24:1 25:16 44:16 66:1 140:12 195:21 248:10 262:6 277:12 320:11 331:13 353:8 involving 19:9 153:20 347:1 irrelevant 143:23 irritant 166:6,11 167:2 243:17 338:9,18 irritants 274:9 irritation 127:24 128:3 140:14 167:7 168:23,24 179:19 268:11 268:12 276:19 isolated 228:24 IS RTP 31:7 issue 37:10 42:19 49:22 52:10,17 53:1 57:21 64:12 65:4 67:18 69:17 73:4,5 73:23 74:8 78:17 81:18 83:6 86:15 87:18 92:16 95:19 96:7 97:15 99:7,13 103:17 105:4 107:23 109:23 123:2,6,11,23 124:8 126:23 132:25 142:1,1	146:15 150:16 154:9 163:17 165:17 167:3 180:18 182:3 182:17 186:25 187:8 191:18 193:14,23 205:6 216:9 217:11 220:10 225:5 226:3 227:22 231:2 232:11 241:22 243:12,12 244:18 245:7 245:14,20 246:24 247:20 249:16 252:8 260:22 262:6 272:9,9,16,24 273:14 277:16 280:3 283:1 291:12 292:23 292:24 293:1,3 294:17,23 296:3,6 304:11 305:7 314:20 321:9 323:20 324:17,19 325:14,25 326:23 330:22 331:15 333:21 333:22 334:15 335:14 350:25 351:4,22 352:2 356:2 362:23 370:2 issued 24:12 109:9 110:24 113:11 issues 30:20 67:1,5 72:18 97:17 117:13 123:10 182:22 182:22 192:1 287:23 294:18 312:19 314:9 324:12 334:9
--	--	---	--	--

335:5 346:2 355:21 360:12 366:5 issuing 56:17 It'll 69:6 Italian 136:22 Iturrulde 16:6	316:16,16,21 316:21 317:6,6 317:9,9,20,20 317:21 318:3,4 318:9 327:24 327:25,25 337:3,4 368:4 368:5	77:23 84:12,14 84:24,24 86:16 99:7 105:13 156:24 217:25 320:7 judgments 86:23,24 88:17 June 20:12 111:19	know 19:23 29:7 34:4 37:17,24 40:9 46:1 51:9 55:16 56:3,6 57:7,19 58:7 59:2 60:5 63:10,16,22 68:12 69:3 70:7 81:1 82:23 85:6,7 85:13 89:20 91:9 92:15 98:25 104:13 105:9 107:18 109:12 110:16 119:3,12 120:23 121:9 122:15,16 130:11 134:17 136:11,17 139:18 140:5,8 143:21 145:2 146:24 150:25 155:8 168:10 168:11 169:13 182:7 183:23 189:23,25 190:3,15 192:3 194:15 196:9 204:25 205:20 206:3 216:6 222:2 225:6,10 225:11,14 229:13 237:9 242:2 243:7 245:22 247:3 247:10 250:19 252:18 257:18 259:18 263:7 263:22 270:15 274:19 277:22 278:21 279:4 279:15,21 287:18 289:21 289:25 292:15 293:19 300:24 301:13 303:4	304:13,20 306:25 307:7 308:7,17,25 309:1,2 312:17 315:5 317:3,16 320:15,19 328:17,17 330:23,24 332:12 339:15 339:19 344:11 344:13,14,14 344:16,25 346:7 352:22 353:1,2,18 354:12,14,22 354:25 355:5 355:10 356:23 357:1,1 369:7 knowing 144:21 194:20 297:24 314:3 328:11 knowledge 34:5 293:11 316:14 355:11 known 29:24 31:2 56:25 128:1 170:23 178:15 184:5 185:4 194:17 196:1 197:24 246:11 256:17 269:6 271:17 272:18 273:12 279:25 285:16 370:10 Krewski 117:18 Kunz 68:19
J	Johnson's 8:11 19:9 34:12,18 40:12 80:4 117:2,24 124:7 126:13 129:18 129:20 130:3 132:4 133:21 136:1 141:1 143:3 144:6 148:9 153:23 154:11,18 155:17 157:4 160:9,23 161:13 163:20 164:4,18,19 165:8 167:19 169:10 170:8 173:20 176:4 176:23 180:5,6 188:11 189:18 198:1 200:3 248:1,5 249:11 249:14,22 250:14 251:16 252:11,15 255:24 256:20 258:4 260:2 261:7 262:22 263:20 274:24 308:19 317:21 318:10	K		
J 3:2 J&J 58:21 250:8 307:21 Jacob 3:20 6:3 Jane 3:1 7:10 287:17 jbockus@dyk... 3:2 Jean 164:9 Jersey 1:1 6:13 Johnson 1:3,3 2:24,25 6:9,10 7:13,13,15,15 7:24,24 8:6,7 10:18,18,24,25 11:19,20 21:9 21:10 30:24,24 30:25,25 34:17 129:18 130:3 132:4 137:9,10 139:16,16 144:16,16,18 144:18 148:9 154:6,6,15,15 154:18 158:18 158:19 160:5,5 160:9 161:23 161:23 164:4 164:19 165:8 180:6 189:17 200:3 251:6,6 251:24,24 253:10,10,14 253:14 268:22 274:23 287:10 287:10 308:12 308:12,19,21 308:22 309:4,5	joined 19:4 Journal 27:11 346:11 journals 27:12 346:10 judge 87:13 247:2 judgment 39:5	Kansas 1:20 372:22 KATIE 3:18 keep 18:9 55:4 80:5,24 81:8 286:16 358:18 358:24 key 56:21 57:2 97:16 169:2 355:20 370:4 Kimberly 2:21 7:14 8:5 kimberly.bra... 2:22 kind 30:13 76:13 81:8 82:9 83:10 114:16 160:17 160:21 194:18 213:12 287:12 293:21 kinds 36:16,22 43:16 57:8,14 58:15 92:25 98:15 101:20 175:15 185:24 187:20 209:18 231:8 271:10 305:6 323:16 KIRKLAND 2:21 Klaassen 357:1 Klimisch 206:1 207:11 knew 57:18,19 57:20 361:7		304:13,20 306:25 307:7 308:7,17,25 309:1,2 312:17 315:5 317:3,16 320:15,19 328:17,17 330:23,24 332:12 339:15 339:19 344:11 344:13,14,14 344:16,25 346:7 352:22 353:1,2,18 354:12,14,22 354:25 355:5 355:10 356:23 357:1,1 369:7 knowing 144:21 194:20 297:24 314:3 328:11 knowledge 34:5 293:11 316:14 355:11 known 29:24 31:2 56:25 128:1 170:23 178:15 184:5 185:4 194:17 196:1 197:24 246:11 256:17 269:6 271:17 272:18 273:12 279:25 285:16 370:10 Krewski 117:18 Kunz 68:19
				L
				lab 310:23 label 47:3 labeled 166:11 labeling 44:9 51:8 52:16 laboratory 181:22 182:20 laid 40:22 59:10

87:11 113:21	lead 97:2 191:23	258:21 266:4	110:12 285:3	139:3 147:13
154:7 158:25	195:19 220:15	282:10 286:9	318:7,9	148:3,8,14,22
164:23 216:12	221:22 227:19	306:25 311:13	linked 42:12	149:12,14,15
333:15	228:23 267:1	338:18 348:1	167:2 227:20	150:22 151:13
landing 181:12	268:23 273:24	348:13,15	228:1 238:6	151:16 152:18
language 28:4	279:5 283:14	levels 161:11	254:16 277:7	152:21,23
45:18,19 46:21	296:22 312:23	166:22 168:15	285:17 338:17	153:8 154:2
47:2,20 48:2	leader 107:12	175:11 176:12	linking 57:4	170:3 180:25
48:16 49:7	leading 107:19	176:21 228:21	58:20	182:8 187:14
50:18 52:10	107:20 222:24	229:4 251:8	lipsticks 161:17	199:19 200:8
110:16 315:24	281:14	256:7 267:16	list 22:1,6,8	200:18 206:23
316:5 333:24	leads 129:12	310:14 311:16	55:10,13 59:13	209:25 223:4
339:20	220:6 313:9	311:18 312:18	59:25 60:1,15	236:9 248:25
large 44:19	leave 366:13	312:21,22	60:20 61:2	249:2,21
53:22 61:23	led 215:11	LEVIN 2:12	63:6,12,13,17	266:15 273:8
128:17,21	329:24	LHG 1:5	63:21 64:1,2,7	273:11 281:3,5
129:11 130:4	legal 24:16	liabilities 73:9	64:11 68:23	282:17 285:13
178:5,7,21	length 265:17	liability 1:5	83:3 108:16,21	286:23 297:9
243:9,12	lesions 222:25	351:18	108:22 109:2,4	299:12 311:3
large-dose 243:3	230:24 240:14	libraries 26:12	118:19 120:15	312:11 314:5
larger 21:25	lesser 324:19	library 26:10,11	122:6,7,9,18	321:13,17,23
22:7 68:23	let's 14:4 16:21	62:22 63:1	211:9 212:1	litigation 1:5,21
125:8,25	20:10 21:5	lies 360:15	241:15 250:13	3:20 6:4 10:17
128:13 129:1	63:7,24 70:23	life 187:5 200:16	263:14,14	12:7 19:9 29:4
late 9:3 317:10	102:18 110:21	228:12 302:2	listed 55:10	131:9 218:20
Laura 1:12 4:13	128:7 151:20	303:19,20	59:13 63:5	246:1,4,22
4:14,16 6:14	180:3 184:18	lifetime 185:17	108:15,17	248:10,13,14
7:20 14:15	188:16 189:11	185:20 187:17	111:1 197:8	248:18 249:7
372:5 374:12	235:8 321:16	200:10 263:21	211:24 310:17	261:20 320:12
law 39:19	327:2 333:13	Lily 164:9	310:18 347:5	320:20 324:1
lawful 7:21	352:19 359:20	limit 170:15	354:23	331:13,22
lawyer 352:12	362:21 363:8	228:5 241:22	listened 32:21	346:17,17,18
352:15	letter 27:13,17	310:15,24	literally 346:4	346:21 347:1
LAWYER'S	361:23 362:1	311:9	literature 25:22	351:1
376:1	363:18,20,21	limitations	57:16 61:14	litigations 29:9
lawyers 350:20	363:23	79:16 239:13	62:3,18 68:24	little 31:11
351:18	letters 27:8	241:5 347:11	71:15 77:25	38:10 39:16
lay 66:22 77:16	level 37:20	347:17	78:11 79:2,7	42:18 44:19
77:24 79:19	39:17 117:15	limited 169:7	79:10 82:25	45:23 53:5
98:3 134:19	121:8 132:2	283:12 312:24	85:5 90:24	61:1,25 67:4
135:9 138:25	145:20,22	358:17	97:8 103:10	81:18 84:5
153:2 158:20	159:17 198:4	limiting 264:11	121:23 125:2	95:4,24 96:6
215:2	213:15 214:2	line 359:10	126:21 128:22	97:3,6,20 99:2
layer 229:24	216:7 217:19	375:3 376:3	128:24 132:18	120:3,9 121:2
laying 151:11	226:19,20	lingering 183:9	132:20 133:1	193:24,24
332:22	227:8 228:16	link 61:19 99:17	133:15 134:20	201:5 203:20
lays 76:12 92:5	229:18 258:21	109:17 110:12	134:22 135:6	210:20 211:3

245:13 335:21 338:1 339:7 365:9 liver 233:25 lives 345:2 living 81:9 294:3 LLC 3:15,15 7:6 7:7 LLP 2:8,21 3:7 3:12 Loansome 26:9 local 26:10 locally 242:16 Locke 3:7 4:7 7:3,3 111:14 111:21 319:1,4 319:5 322:9 323:1 325:15 326:21 329:7 329:19 330:12 333:1 336:4 337:11 340:24 343:10 351:14 352:6 354:4 356:19 357:10 358:11,16,20 359:3,11 364:14,20 368:19 long 18:18 179:4 304:23 343:24 358:20 369:7 long-term 72:20 178:19 longer 95:6 220:21 303:2 305:11 359:4,7 Longo 163:19 177:15 249:3 259:17 Longo's 162:7 247:24 248:18 248:22 look 19:22 21:13 22:3 27:19 29:23 31:2 36:22 49:12	51:11 52:1,3 53:24 56:18 60:4,6 62:9,10 68:20,25 72:16 75:15 78:25 79:13 82:24 83:11 84:15 85:11 91:1 92:3,4,10,16 92:25 96:22 97:23 98:10 105:1,25 106:5 109:19 110:17 110:19 117:4 118:18 119:7 119:10 130:16 133:14 134:1 143:10 145:2 146:7 150:17 153:18 155:25 159:10,12,14 159:24 160:8 160:16 162:7 162:16 166:24 170:22 172:21 174:20 177:6 182:3,17 183:21 189:22 195:11 202:15 208:6,13 210:11 221:5 225:3,4 229:4 232:5,11 234:3 237:19,20 239:12,15 240:6,10,13,23 241:7,12,15 245:20 246:25 247:7 248:20 249:13 252:1 254:18,24 256:13 259:19 263:9 267:23 274:6,19 275:21 276:17 277:14 278:5 280:5,11,11	281:19 282:23 284:10 288:5,6 288:10,21 291:14 292:2,7 293:3,6 295:17 315:14 317:13 317:15 318:15 320:6 323:2 324:25 326:23 327:5,11 334:10 338:20 361:16 364:5 364:10 367:5,7 368:14 looked 15:4,8,18 15:20 16:5,6,9 17:3 52:15,16 69:25 70:19 73:3,5 98:1 109:11 123:21 142:9 159:20 161:1 163:11 163:16,22 165:17 173:11 175:13 179:20 185:22 187:8 192:21 217:8 224:14 238:7 238:24,25 239:1 256:25 271:23 278:19 285:1 304:4 319:9 333:8 336:25,25 338:10 348:17 looking 19:7 31:21 32:18 36:4 37:15 40:5,6 48:7 49:21 52:11,20 53:19,21 54:21 55:13 61:15,21 64:18 68:13 74:7 76:8 78:6 80:21 81:22 83:16 86:7,16 88:1,9 93:2	112:9,11 115:18 117:2 117:11 119:4 119:17 123:13 131:5 132:17 138:12 141:11 142:6 145:9 152:2 153:5 162:12 169:14 170:18 171:13 194:16,17 195:21 207:21 218:13 225:6 225:12 226:2 231:1 239:18 240:3,4 257:2 258:15,17 262:7 272:25 273:17 277:17 293:1 294:20 302:18 315:21 320:8 324:19 325:25 326:1 327:4 330:22 331:15 336:14 352:2 looks 41:17,18 41:19 197:14 197:14 Loretz 365:15 365:22 Los 2:23 lot 27:10 44:19 61:10 79:1 170:12 182:6 229:12 271:14 315:8 346:1,2 350:19 lots 62:9 267:4 Louis 1:15 3:14 6:9 19:19 20:21 love 230:25,25 low 145:22 235:10 256:7 258:20 319:11 lower 68:6 69:15	73:15 183:16 229:8 295:4 328:2 lung 125:5 178:20 179:19 231:3,8 254:22 264:22,23 291:15 lungs 178:19 <hr/> M M 3:12 4:13,15 4:16 ma'am 312:14 macrophage 125:7 macrophages 150:17 magnitude 293:7 main 97:12 maintain 319:11 maintained 59:25 62:16 majority 74:2 141:22 142:23 160:13 184:9 makeup 355:18 making 37:1 44:17 74:5 173:2 243:14 245:24 253:7 261:15 317:11 318:2 338:24 male 103:12 manner 231:24 232:17 265:25 manual 76:10 manufactured 137:9 139:15 154:5,15 158:18 160:5 164:19 165:9 316:15 manufacturer 309:5 331:16 manufacturer's
---	--	--	--	---

Confidential - Pursuant to Protective Order

Page 402

329:21	211:25 212:10	143:7 144:9,24	325:5 330:6	321:17,22
manufacturers	263:8,10 321:7	154:21 155:18	331:4 346:18	359:16
144:12 359:24	333:8 342:4	166:14 173:22	347:7,22 350:4	medicine 26:11
360:4,7,19	Mattenklott	174:9 179:12	353:25 360:6	27:11 353:24
mark 8:17 13:5	250:3	180:17 183:8	361:23	354:16,19
13:13,15 14:1	matter 21:14	192:18 221:4	meaning 47:24	meet 114:23
14:4,13,21	60:8 186:1	222:10 234:12	189:9 264:13	meeting 12:8,9
16:22 17:12	235:9	252:17 260:4	means 50:19	18:14,17,19,24
111:8 211:17	Matthew 261:7	298:21 303:14	99:1 118:20	19:1 343:16
marked 8:13	MDL 1:4 8:10	304:16 306:9	127:3 310:23	344:17,20
13:18 14:10,18	11:8,21 13:8	307:13,23	meant 35:8	345:7
14:24 16:16	14:23 22:19,20	308:6,15	140:6	meetings 31:7
17:9 20:4	23:1,7 24:3,12	309:16 310:8	measurement	344:2,6,8
22:21 23:9	29:4,10,17	312:5,9 315:4	177:16	member 344:22
25:19 28:1	31:21 32:21	316:22 322:20	meat 30:2	members
53:6 90:8	33:4,10,20,24	325:3,21 327:7	mechanism	353:19 354:11
93:15 95:11	34:1,8,12 35:1	329:11 330:2	88:11 140:12	356:8
111:4,12	58:1 61:7,9,15	332:9 334:20	179:8,10	memory 12:16
155:13 201:10	65:14 66:11	337:9 342:23	188:11,25	362:5 367:21
206:15 209:23	74:14,21 75:1	350:21 351:19	189:9,16,24	mention 90:3
211:14,20	82:18 83:1	356:12,24	191:19,22	119:20,21
266:21	85:15,24 87:6	358:10,14,19	192:4,14 193:1	147:5 168:9
market 2:18	89:7,18 91:23	358:25 359:8	193:5,16,19	340:8,9,13
43:16 154:12	113:11 115:17	368:21	194:3,6 195:13	347:10,14
160:17 161:4,9	116:24 117:23	mean 11:8 13:9	195:17 196:6	mentioned
308:13 326:8	118:15 139:12	21:19 28:7,12	196:13 219:24	18:12,23 31:19
329:16	157:2 160:3	28:13 38:5,6	221:10,20	33:19 35:3
marketed 43:14	188:15 198:3	39:24 41:13	223:1 227:18	118:21 121:21
marketing 1:4	203:15 214:13	53:14 56:3	228:3 229:15	148:13 163:4,5
6:10 322:17	216:23 236:3	58:11 70:17	268:10,12	209:12 264:2
324:4	255:25 261:12	72:4 83:23	272:20 276:4	282:22 314:6
markets 324:9	262:4 267:8,22	85:10 89:21	277:7,17 278:2	327:3
marking 14:6	268:9,21 269:3	105:10 109:25	278:6,12	mesh 129:7,7
markings 13:23	269:8 285:3	116:2,12,22	281:16 282:12	130:13
16:24	288:2 335:7	120:18 124:22	289:3 293:5	mesothelial
match 231:9	Meadows 2:3	127:7 131:19	314:21 370:7	233:20
material 61:10	6:18,18 13:12	131:23 135:16	mechanisms	messed 339:5
82:19 175:14	18:16 23:14	137:17 152:17	146:20 189:13	met 18:13
208:9 263:14	24:4,15,25	154:25 181:21	191:11,13	287:17 319:7
307:21	28:21 32:3	183:18 189:4,5	228:5 274:7	Meta-Analysis
materials 9:17	38:19 39:22	196:23 197:9	275:23 281:22	4:19
20:24 21:19	40:17 51:2	216:5 232:4	mechanistic	metal 264:7
45:6 57:25	56:7 58:6 86:2	236:21,22	195:22 217:1,5	310:11 311:3
68:14,22 82:20	93:17 94:10,13	247:13 254:24	medical 26:10	311:14 312:17
83:23 108:18	106:12 131:17	263:13 275:5	27:12 62:2	312:21,22
122:6,10,11	132:5 134:15	281:9 294:15	147:13 157:24	313:3
175:15 208:3	136:3 139:17	301:18 320:5	266:15 321:12	metals 146:14

264:1 267:1,18 268:1,6,8 269:5 272:3,7 272:10 273:3,9 274:22 275:7 276:10 278:14 288:1 289:2 293:19 309:19 310:3 311:3,24 methodologic... 155:12 methodology 75:16,19 76:4 90:21 114:24 116:23 117:1 117:22 173:16 methods 214:22 214:24 236:8 METHVIN 2:2 Michelle 2:8 6:20 microenviron... 228:25 microns 124:25 124:25 125:1 microphone 339:6 middle 316:13 migrate 64:24 68:6 69:14 70:5,22 72:11 73:15 182:10 185:5 283:13 migrated 300:14 migrates 181:19 183:5 186:16 301:14 migrating 185:11 migration 66:5 67:9,15 69:10 69:17,21,24,25 71:2,10,17 73:24 74:6 81:2 95:19 97:12,15 100:6 182:13 184:3	215:7 216:9 295:22 299:22 300:1,9 335:14 356:2 migratory 71:24 MILES 2:3 mill 178:1 milling 132:24 million 158:5,5 millions 53:22 53:22 Millman 250:5 mind 14:1 38:8 mine 130:24 136:22,23,23 142:8 145:6 357:9 mined 131:14 135:22 142:15 miner 175:8 178:1 mineral 253:20 254:2 minerals 250:10 309:10 311:23 mines 136:25 142:16 150:1 minimize 202:20 minimum 303:5 303:6 mining 132:24 135:11 175:16 minute 208:14 219:24 364:9 minutes 288:9 299:6 356:14 misheard 298:13 missed 137:19 316:3 missing 200:7 297:19 Missouri 1:15 1:19 3:14 6:9 372:20 misstates 86:1	163:3 186:12 296:18 mistake 69:8 mistaken 108:24 MITCHELL 2:12 mixes 308:22 mixture 125:18 146:12,17 151:25 152:2,5 152:8 153:7 167:9 168:21 169:15,16 225:7 226:3,9 256:2,15,16 257:3,10 272:23 277:11 277:21 mixtures 292:24 mode 278:5,5 289:8 292:25 370:5,10 model 182:12 modified 65:20 molecular 189:24 moment 12:19 74:13 99:20 242:8 Monday 9:4 12:8,11 18:13 18:15,17 money 349:22 350:19 351:17 351:25 monitor 235:17 monkey 182:23 monkeys 182:21 182:23 monograph 288:17,18 monographs 149:17 Montgomery 2:6 month 11:1,10 11:18 300:2,25	301:2,2 303:13 303:16,19,20 303:21,25 304:15 305:2 305:14 months 301:3,18 Moon 250:3 morning 8:3 306:21 327:22 morphology 147:24 149:6 motion 180:10 mouse 292:1 move 70:10 73:10 125:6 180:9 183:15 265:4,10,12 moved 112:14 movement 71:5 73:6 74:8 103:14 105:4 183:20,25 184:10 moving 358:18 358:24 mparfitt@ash... 2:9 multiple 27:4 169:24 256:2 275:21,22 301:23 multiply 292:15 Muscat 244:11 246:2 361:8,14 361:25 362:15 363:24 364:3 364:23 365:4 365:24	287:17 319:9 327:23 344:14 name's 319:5 names 149:12 289:22 349:17 narrow 11:6 28:18 33:20 57:7 narrower 61:25 Nate 164:9 nation's 107:12 National 4:24 26:11 107:9,16 108:6 110:5,24 112:6 113:9 natural 223:7 225:15 228:14 naturally 310:12 311:5 nature 48:19 55:22 133:12 212:19 258:18 266:6 NCI 110:4 113:16 NCRA 372:18 near 348:14,15 necessarily 21:22 116:18 197:9 214:2,6 225:25 227:23 231:25 265:24 268:16 269:20 276:5 necessary 47:5 47:16,25 48:19 49:8 50:2,19 51:19 52:19 286:4 373:4 need 9:12 39:18 39:23 45:17 52:17 62:3 105:25 110:19 119:10 146:6 151:12 206:4 213:9 221:1 229:22 231:13
---	--	--	---	---

233:3 244:9	291:6 293:15	88:3,24 142:4	58:6 72:2	307:13,23
247:17 274:19	312:4 313:10	222:19 230:25	73:17 75:5	308:6,15,16
276:16 278:1	night 16:7 18:24	240:16	85:25 86:2	309:15,16
280:4 292:12	NIH 26:11	number 9:8 14:7	87:8 89:19	310:8 312:5,9
306:5 347:8	nine 183:24	14:11,14,18,20	90:12 91:24	315:4 316:22
355:23 359:5,6	noise 365:9	14:25 15:7	93:17 94:10,14	321:20 322:20
361:16 362:4,5	non 294:13	16:23 17:14	96:9 99:5	325:3,21 327:7
364:4,6 365:16	non-asbestifor...	20:4 96:22	105:23 106:12	329:11 330:2
366:16,19,20	147:15 148:25	111:9 112:6	106:13 107:14	332:9 334:20
366:23 368:13	149:18 151:7	122:19 126:20	113:19 118:16	337:9,10
needed 48:15	193:3	133:5,8 142:16	121:3 126:25	340:21 342:23
213:16	noncancer	158:2 172:3	130:6 131:17	342:24 350:21
needing 264:17	294:16,24	174:7,11	132:5 133:25	350:22 351:19
needs 52:12	nondirect 281:8	185:13 189:12	134:15 136:3	351:20 353:22
94:17 167:11	nongeno 294:15	211:18,21	137:11 139:17	356:12,24
264:8 328:3	nongenotoxic	241:2 258:15	141:2 143:7,8	objections 18:2
352:4	280:20,25	302:5,7,21	144:9,24,25	observations
negative 42:3	281:21,24	303:3,5,7	145:23 154:20	184:8 226:22
negatives 79:18	282:9 294:13	304:1,2 347:4	154:21 155:18	270:19
neither 372:11	Nonhuman	347:8 348:16	157:7 159:7	observe 230:24
372:12	206:25	354:11	160:10 162:1	observed 222:5
neuronal 233:24	nonlitigation	numbers 22:6	163:2 164:11	227:24
never 43:21 52:8	213:25 218:19	58:25 100:17	165:11 166:13	observing 222:6
58:8 205:20	nontremolite	177:20,21	171:5 173:22	242:22
246:11 255:16	149:23	348:9	174:9 176:5	obviously 28:24
293:12	normal 222:3	numerical 86:11	179:12 180:16	41:21 57:16
new 1:1 6:13	279:20	87:3,10 89:3	184:24 186:11	83:4 93:6
27:10 33:5,10	normally 220:8	101:2 103:24	187:18 190:14	122:15 135:13
54:15,15,18	North 1:14	105:14,19	192:18 195:6	153:17 196:19
55:16 61:15,23	Notary 372:22	106:10 107:6	196:8 198:8	219:12,17
62:4 78:23	374:19	114:18 115:9	214:17,18	229:24 239:12
135:23,25	notation 317:12	134:4 141:7	221:4 222:10	314:16
140:24 211:9	notations 16:25	160:22 219:4	233:6 234:11	occasional
211:24	note 82:24	315:18	234:12 238:14	218:25 283:2
news 122:19,21	218:10	Nurses' 312:15	239:22 241:19	occupation
123:11	noted 373:10		252:16,17	175:7
newspaper	374:7	O	255:10 259:10	occupational
124:3	notes 80:16 81:8	O 3:19	259:13 260:4,5	174:21,25
Newton 16:7	376:1	object 28:9	261:10 262:24	175:2,10,19
nice 101:16	notice 4:11 9:9	183:10 369:23	270:14 278:16	176:13,22
168:10	9:16 17:17	objection 23:14	279:14 282:3	177:22 178:11
Nicholson	141:24 173:4	24:15 28:21	283:24 284:18	occupationally
365:19	290:25	32:3 33:8	291:9 292:20	132:23
nickel 267:2	November 4:17	38:19 39:22	296:4,17 298:6	occur 71:10
268:2 276:16	14:22 22:20	40:17 45:1	298:21,22	175:25 179:1
276:18,20,22	NRC 76:11	48:22 49:10	300:3 303:8,14	184:5 194:23
278:11 279:5	NTP 31:8 57:6	50:5 51:2,3,23	304:16 306:9	194:25 295:3

303:24 311:7 342:11 occurring 226:7 310:12 311:5 occurs 131:13 186:10 253:21 299:19,22 300:1 October 4:13 14:8 19:14 21:4 offer 34:11 43:3 203:15 offered 33:6 34:24 60:12 262:18 320:16 offering 33:3 60:3 157:2 268:21 269:3 office 53:17 56:13 official 14:2 offset 292:17 oh 60:9 69:9 267:10 269:9 313:14 348:23 355:22 361:20 okay 8:22 9:5 10:5,22 11:9 12:19 14:1 18:12,23 19:7 20:18 22:12,17 23:6,11 25:9 26:3,22 27:20 27:24 29:16 32:15 33:12 39:15 43:2,7 44:4 46:16 53:4 55:4 56:7 60:19 61:5 62:13 63:2,14 64:15,18 65:13 66:9 68:9 69:2 69:20 74:23 75:15 76:2 77:12 78:21 80:1 84:4	85:19 89:13 91:12,17 94:9 95:10,16,23 96:18 100:2 107:22 109:1,8 110:22 113:15 114:25 115:10 115:15,15,23 116:23 118:12 119:4,24 121:20 122:4 124:3,11,13,19 126:11,19 127:14 128:4 131:11 133:4 133:18 137:22 140:4 142:25 145:16 146:2 146:25 147:11 147:19 151:14 152:1,10 153:25 156:21 158:12 161:10 162:21 164:7 165:7 166:2,14 170:4 173:15 174:14 175:1 180:2,17 181:10,17 182:4 186:6 187:12 188:1 189:11 190:23 192:11 193:22 194:1 196:19 197:7 200:19 201:16 203:16 206:7 207:16 208:8 210:5,18 211:6 212:3,15 215:15 217:17 218:21 219:23 221:24 227:12 232:18 234:20 235:6 236:1,6 242:7 243:23 250:17 259:21 260:25 263:12	264:18 265:15 266:24 267:14 267:21 269:4 269:10,10,15 270:10 271:24 274:17 276:24 277:10,25 280:17 281:23 284:12,25 285:24 286:8 286:14 288:7 288:22 289:25 290:2,2,5 306:13 308:2 318:11 324:2 329:8,20 340:2 341:15,18 345:14 351:15 352:19 359:3 362:4 365:8 367:18 old 18:8 older 15:17 111:2 OLVEY 2:21 omission 98:25 121:1 omitted 96:16 98:8,10,19 once 43:15 60:1 67:3 187:3 261:20 290:23 300:1,1 301:2 oncologist 358:4 359:13,15 one-expert 348:12 one-to-one 271:4 ones 16:2 26:21 53:25 70:13,18 76:19 81:3 101:5,6 119:23 122:12 123:21 138:19 148:6 170:24 229:17 234:16 254:2	268:9 362:17 online 26:12 open 344:2,4 opening 296:23 operate 278:11 278:13 operating 272:14 Ophthalmology 355:8 opine 31:20 33:24 opined 33:22 257:2,5,7 opinion 34:12 34:17 35:1 37:1,22,22 39:19 41:1 43:3 66:22 70:3 86:19 95:8,21 125:13 125:15 128:6 128:10 144:6 145:25 146:3 147:19 149:1 151:19,22,23 160:2 164:2 166:17,18 167:10 175:23 176:1,7 181:14 182:11 183:6 184:11,15,17 184:21 185:1,6 185:7 186:6,22 186:24 188:24 189:15 190:9 190:16 191:4,6 191:14,20 193:8,12 196:4 197:25 198:14 199:3 200:1,5 203:9,9,12,13 203:14,17,19 204:15 208:22 212:9 213:14 216:10 219:9 236:17 237:2	239:17 244:6 256:22 257:12 259:22 260:7,8 260:21 261:3 262:4 265:11 265:13 268:21 269:2 274:11 277:10 280:24 285:2,14 286:3 286:7,8,12,22 298:2,17 299:15,16,25 300:5 303:10 303:23 304:1 304:22 306:7 306:17,19,22 307:1 316:7 318:4 319:15 319:17 321:1 321:19 324:21 329:24,25 332:4,6 333:21 338:7,12 339:1 339:10,13 346:19 353:16 354:1,9 355:12 355:16 356:10 358:8 opinions 10:24 21:22 22:10 28:3 29:19 30:13 32:6,18 32:23 33:3,6 33:10 34:2 53:13 60:3,12 61:7 66:16 75:1,17 76:5 80:2 81:11,24 82:14 85:17,17 85:24 89:6,17 109:22 110:2 116:13 125:16 151:17 157:1 174:11 191:16 192:7,8 215:12 216:21,23 226:17,21
---	---	--	---	---

237:5 244:10	83:1,2 314:15	273:6,10,13,15	35:18	348:20 355:14
262:18 306:4	373:14	274:13,14,25	overlapped	355:18 356:8
307:8,20	originally 19:15	275:6,16	11:25	357:2,22 358:7
314:14 320:21	outcome 35:5,19	282:19 285:4	overlaps 350:24	panel's 121:22
320:22 322:14	38:18 39:21	286:4,18,23	overview 30:6	panelists 349:5
323:9,24	40:13 244:5	288:20,24	overwhelming	panels 348:14
330:19 333:15	outline 80:22	289:13 291:12	154:12	Paoletti 250:2
335:10,15	90:9 188:14	291:18 306:18	overwritten	PAPANTONIO
337:18,21,25	outlines 126:8	306:24 312:8	80:21	2:12
339:4 355:17	outside 105:5	319:18 321:2	owns 44:19	paper 15:20
opportunity	116:18 117:1	322:5 324:6,12	oxidative 227:13	71:4,16 72:15
297:10 298:25	141:24 228:15	325:1,17	228:2,6 277:8	73:1 81:3,3
299:4,10,11	286:23 295:25	326:24 327:6	278:23 279:2,6	93:12 103:16
opposed 54:10	296:6	330:1 331:5		105:3 117:10
134:13 140:24	ovarian 4:20,23	332:7 335:17	P	138:3 162:10
205:22 255:5	34:13,19 37:4	369:22 370:14	P 2:1,1 3:19	195:10 209:1
266:10	40:14 57:1,21	ovaries 64:25	P.A 2:12	239:25 247:15
oral 4:11 9:9	61:18,20 80:4	180:7,12,14	P.C 2:3,16	250:23 251:15
oranges 120:8	108:8 109:18	181:2,20	p.m 188:4,5,7	284:17 321:22
order 1:9 14:5	110:7,13,25	182:14 183:5	200:22,23,25	351:23
26:6 30:10	111:2 112:8,24	183:17 184:14	287:4,5,7	papers 15:17
36:25 38:14	119:6 124:6	184:23 185:21	364:16,17,19	80:13,13 104:2
39:18 48:13	125:10,12	186:9,20	368:25 369:1,3	104:7 117:18
52:1 82:20,22	127:21,23	187:16 243:1	370:25 371:3	138:3,8 149:22
82:24 92:23	151:21 156:11	305:22	page 4:2,10 53:8	182:8 215:9
106:17 114:22	157:6 160:4	ovary 101:19	53:9 64:3,20	246:6 314:3
202:20 221:2	165:10 169:3	181:8 288:3,13	65:15 100:3	322:2,6
231:3 232:25	173:21 176:2	298:5,20	112:10 147:9	paragraph
264:6 282:5	179:10,23	overall 54:6	183:12 206:21	15:13,24 16:1
326:16 365:17	180:25 181:11	71:17 73:21	206:22 212:16	46:24 53:7,9
ordered 62:23	188:13 189:1	81:4 85:9	236:4 242:9	54:8 64:16,19
ore 130:24	189:18 190:12	120:10,15	267:13 280:19	65:15 66:10
organism	191:1,23 192:5	123:2 125:20	289:17,23,24	68:1,17 75:7
294:10	192:17 193:4	126:12,23	313:14,17	76:18 77:19
organisms 294:3	193:17 196:2,7	127:12,16	316:12 318:16	78:23 80:25
organization	196:22 198:3	141:19 143:18	336:19,20	90:20 92:4
353:15 354:10	198:22 200:5	150:7 159:11	337:14 367:7,8	95:12,16
organizations	202:12,18	168:17,18	375:3 376:3	100:17 102:19
349:24	203:6 204:16	169:21 173:2	pages 374:5	103:2 124:12
organize 196:14	207:22 208:23	187:14 207:10	paid 244:3	124:14,17
organs 117:13	220:1 221:25	215:21 229:20	350:13,19	126:4 133:6
146:19 235:18	222:9 236:19	241:13 246:16	362:17	134:21 147:8
original 20:23	237:4,15	314:12 319:14	panel 95:17 96:1	147:12 150:16
21:2 22:4	238:10,12	348:25 355:17	96:21 97:13	166:3 168:7
29:12 32:7,9	239:19 241:23	overdose 178:9	100:4 120:24	177:5 183:12
54:22 68:14,18	256:23 258:1,3	overlap 28:13	121:11,13	188:18,20
68:23 74:19	269:1 272:2,24	28:14 33:17	342:4 348:12	190:7 212:18

236:3,7 242:9	162:1 163:2	209:5 210:9	145:6 174:7	pause 99:19
242:12 249:10	164:11 165:11	211:6,8 213:19	185:1 205:16	246:10
249:19,24	166:13 171:5	215:21 234:21	210:8,24	pay 62:25 84:17
250:13 251:1	176:5 180:16	236:2 238:4	217:20 218:4	253:5
266:16,23	184:24 186:11	241:1 246:24	220:25 226:19	PCPC 31:1,23
267:23 272:10	187:18 190:14	268:19 285:2	226:20 228:8	32:2 58:24
280:19 281:4	195:6 196:8	288:22,24,25	244:8 245:1	360:11 362:3
289:17,24	198:8 214:17	302:4 304:10	252:13 264:24	363:13 364:2
313:13,15	233:6 234:11	323:3 325:10	274:22 275:15	364:23 365:15
315:21 316:12	238:14 239:22	359:25 369:10	300:15,16	365:23 366:17
336:20 337:15	241:19 252:16	participate	302:5 337:25	367:1,14,22
337:25 338:4,6	255:10 259:10	25:25	346:1 347:22	368:4
340:11 362:7	259:13 260:5	particle 69:17	348:24 349:2	PCPC's 122:2
364:7 365:2,12	261:10,15	69:18 70:12	particularly	361:9
367:8,12,14,17	262:24 270:14	72:12 74:8	20:22 101:6	PDF 80:17
367:19	278:16 279:14	93:4 124:24	104:19 117:2	PDQ 108:7
paragraphs	282:3 283:24	125:8,11,25	175:3 207:20	109:9,17 110:4
12:15,17,25	284:18 291:9	126:1,2 128:8	particulate	113:10,16
13:3 15:4,7,10	292:20 296:4	128:14 150:5	71:17	PDQ)-Health
15:11 22:5	296:17 298:6	150:15	parties 372:12	4:24
75:8 90:7	298:22 300:3	particles 70:1,4	partly 116:14	PDQs 108:2
100:13 120:18	303:8 308:16	70:9,16,18,21	parts 59:17	111:3
366:4 370:1	309:15 321:20	71:19 95:19	218:4 312:7	Pecan 3:3
parameters	337:10 340:21	125:24 126:9	320:22 322:24	peer 116:11
306:4	342:24 350:22	127:20,25	336:11	209:12 216:8
parentheses	351:20 353:22	128:13,23,24	party 366:12	peer-reviewed
65:9 133:10	369:5 370:16	129:1,14,22	pass 180:7	83:12 87:17
parenthetical	Parmley 16:5	130:5 183:15	passage 181:6	90:25 92:17
66:12	102:20,22	183:25 184:3	passed 352:14	313:25 314:5
Parfitt 2:8 6:20	105:2 296:2	184:10 185:5	patent 15:18,22	pending 11:3
6:20 28:9 33:8	part 26:18 30:5	185:10 230:23	352:15	Pennsylvania
45:1 48:22	30:5 40:5 49:1	264:20 265:4	pathogenesis	2:18
49:10 50:5	52:2,9 66:5	265:16 283:13	272:11	Pensacola 2:14
51:3,23 72:2	67:14 76:22	295:23	pathway 175:20	people 16:13
73:17 75:5	78:2 87:5 89:5	particular 26:7	175:23 194:11	18:7 73:3 85:7
85:25 87:8	93:9 103:4	35:5 38:17	195:4	85:14,16 88:7
89:19 90:12	107:2 108:20	39:20 40:11	patients 183:20	160:8,22
91:24 96:9	109:5 115:16	47:11 50:9	183:24,24,25	186:20 187:2,3
99:5 105:23	116:14 122:24	54:7 77:14	184:9	193:11 226:8
107:14 113:19	123:6,24 124:5	78:13 79:7	pattern 41:10	228:9 247:7,10
118:16 121:3	137:3,12 141:6	87:4 89:4 96:5	52:23 71:2,10	247:12 301:6
126:25 130:6	152:8 153:9	97:3,18 98:23	164:3 170:22	301:25 305:20
133:25 137:11	159:23 170:21	102:5,24	239:21 294:8	320:2 352:20
141:2 143:8	171:7,8,9	103:20 104:22	301:11 305:23	353:21,23
144:25 145:23	173:1 177:1	120:4 125:21	313:4 329:6	354:12
154:20 157:7	188:19,19	128:8 132:20	patterns 301:24	people's 195:11
159:7 160:10	193:2 198:12	133:23 137:7	305:6	percent 40:16

40:20 121:5 145:19 167:1 172:10 173:1,5 173:14,19 174:7,8 223:13 338:17 347:11 351:16 366:21 percentage 54:6 161:21 297:17 302:9 347:4 percentages 166:22 167:18 168:1 169:5,8 170:6 183:19 perform 53:10 performance 129:15 performed 55:6 55:7 181:22 207:4 245:19 268:20 331:8 performing 122:23 perineal 4:19 67:10,16 112:12,20,23 119:5 175:24 177:16 183:3 184:12,19 185:18 186:8 193:3,4 198:21 203:21,22 231:11 258:11 260:2 263:20 263:25 291:19 292:4 296:21 297:11 298:19 306:23 perineally 185:12 186:21 187:5 237:14 258:11,24 259:1,5 322:5 329:4 perineum 180:8 181:20 182:14 295:24	period 21:9 82:9 179:4 302:1,21 341:2,6 348:12 355:24 361:12 361:17 365:11 periods 57:6 368:5 peritoneal 4:23 180:11,13 peritoneum 180:23 persist 301:16 person 84:18 366:13 personal 3:10 7:4 31:1 49:6 50:2,22,25 51:22 319:6 353:11 personally 181:17 344:13 349:23 353:2 perspective 328:23 PERTAINS 1:7 pesticides 351:8 petition 359:21 361:19,21 362:11 363:2 363:10,14 364:25 ph 1:22 Ph.D 1:13 4:13 4:15,17 7:20 372:5 374:12 phagocytosis 180:13 pharmaceutic... 227:6 phenotype 220:3,7 221:25 222:3,9 phenotypic 225:23 276:12 279:12,19 Philadelphia 2:18	physical 26:18 physician 107:23 359:18 piece 78:1 84:19 85:4 119:16 120:12 155:1 168:20 172:9 173:9 176:15 205:9 245:1 248:23 250:7 252:13 284:16 302:12 332:1 339:3 370:4 pieces 76:20 77:17 78:13 79:7 80:5 81:12 85:23 87:4 89:4 90:5 90:11 97:8 115:25 116:10 121:23 122:21 125:2 126:20 139:24 208:25 209:25 215:3 218:14,23 304:4 314:7 place 83:14 102:11,12 115:3 131:21 210:22 232:23 299:4 301:22 372:9 places 46:23 193:13 315:9 plaintiff 247:2 247:16 304:5 plaintiff's 322:12,13 344:12,15 346:8 plaintiffs 2:19 6:19,21,23,25 7:2 22:15 246:21 plaintiffs' 4:11 350:20 351:1 351:17	plate 129:22 plateaued 238:2 platy 124:24 130:4,16,18 146:9 150:5,15 223:13,20,21 277:24 293:20 plausibility 34:4 194:7 195:2,9 195:14 268:12 289:3 314:20 370:7,13 plausible 189:8 191:22 194:2,4 194:6,25 195:3 196:13 221:19 227:18 229:14 277:6 369:20 play 117:7 125:11 127:20 146:15 169:19 255:24 268:25 played 246:16 please 6:16 25:8 27:18 249:20 373:3,8 plenty 252:20 pleurodesis 126:5 128:15 129:9 Plunkett 1:13 4:13,15,17 6:15 7:20 8:4 8:13,17 9:8 12:23 13:17,20 14:6,7,10,15 14:17,22 16:16 16:22 17:9,13 23:18,20 24:11 25:4,15 34:11 34:23 44:22 46:7 50:17 63:25 80:2 87:2 88:20 93:11 94:1 95:3 102:10 105:17 110:3	111:4,9,11 112:4 113:6 139:8 140:21 167:24 201:3 211:14,18,20 211:22 236:24 287:8,16 369:6 369:8 370:18 372:5 374:12 point 24:17 25:6 49:5 50:3,12 52:5 56:16 59:20 66:17 67:23,24 71:1 71:21 84:2 90:7 100:16 102:3,10,21 134:21,23 138:14 139:10 140:22 146:21 162:22 163:23 165:14 176:7 176:10 177:4 181:7 192:22 210:21 221:14 225:17 248:22 254:22 261:16 273:8,15 275:14 276:25 281:2 282:16 284:25 288:16 296:10 297:25 300:5 302:12 303:23 304:2 316:9 347:23 362:23 366:2 368:10 pointed 109:4 221:11 pointing 86:9 91:5 152:19 190:7 219:16 226:6 244:9 250:2 276:2 points 31:9 86:13,14 117:12 165:16
---	---	--	---	---

229:6 231:5	295:8 299:8	133:21 141:1	precise 74:23	Prevention 4:24
235:16 254:24	301:24 305:4	143:3 144:7,19	315:24	primarily 166:3
294:25 367:24	312:15 316:8	151:4 153:23	precursor 318:1	334:19
policy-type	316:24 343:21	155:17 157:4	predicate 31:25	primary 4:23
351:11	354:22	160:24 161:14	predominant	136:10
Pooley 250:4	possibly 61:1	162:11 167:19	175:21,22	primed 274:1
pools 78:8	197:3 198:7	169:10 170:8	premarket	principal 136:21
poorly 232:7	potencies	173:20 175:22	329:17	principle 126:8
population	254:13	176:4,24 178:7	preneoplastic	278:7 283:17
159:19 228:11	potency 36:15	180:5 184:12	222:24	294:1
populations	88:15 156:15	188:12 198:2,2	prep 11:25	principles 5:1
157:19 158:14	156:18 157:9	200:3 248:2,5	preparation	36:1 125:24
portion 112:1	158:3 171:23	249:11,14,22	11:25 13:1	209:16 211:11
portions 47:11	225:4,21	250:14 251:4	15:5,8 20:16	275:19 278:4
PORTIS 2:3	254:15 256:12	251:16 252:12	prepare 12:4	290:7 291:1,2
pose 256:7,23	256:12	252:15 253:10	prepared 335:7	304:25
268:18	potent 254:21	255:24 256:20	335:18 361:8	print 201:15
posed 143:20	potential 37:16	258:19 260:2	preparing 25:18	202:13
295:12 322:15	77:6 108:7	261:8 262:22	315:22	printed 17:6
327:16 334:4	127:25 151:20	263:21 268:23	presence 163:18	111:17 201:12
position 28:2,7	157:5 165:8,14	283:2,9 289:15	222:5 227:12	202:23
43:21,25 44:23	166:6 167:7	290:19 293:18	258:18 261:8	printout 4:21
66:4,7 109:16	168:25 178:2	306:23 308:20	273:4 275:21	17:4
110:2,5,10,10	189:13 202:10	309:13 318:3	294:11 295:13	prior 10:8 56:17
110:23 112:5	208:22 238:12	322:16 329:3	305:21 309:23	68:2,3,10 75:9
117:21 120:22	241:15 245:2	369:11,18,21	309:23 312:3	90:4 96:25
145:17 166:9	263:16,25	powders 129:16	present 3:17	346:7,16 372:4
202:7 296:11	266:14,18	130:14 150:25	18:14,25	privilege 23:23
positive 42:2	272:17,19	154:11 161:21	188:13 252:14	54:5
positives 79:18	274:23 275:11	162:25 164:9	259:2 264:7	privileged 23:25
possession 17:22	276:11 278:1	175:14 198:22	369:18,19	probability
possibility	282:19 285:3	251:5,7 253:2	presentation	197:24
196:21 197:20	285:19 289:9	253:4 256:15	20:25	probable 269:6
197:24 255:23	290:21 302:15	267:5 277:22	presents 145:19	probably 9:11
281:13 327:18	327:14,15	277:23 313:9	203:6	11:10,23 18:20
327:19	332:19 350:9	316:15 370:15	president	19:2 23:5
possible 56:4,11	potentially	power 42:19	352:23,24	54:17 60:25
62:21 68:21	207:5 217:11	218:1	354:15 355:2,2	294:15
98:18 109:17	270:18	practice 115:8	Presumably	problem 223:3
155:5,7 186:7	powder 1:3 4:22	116:4 336:1,2	80:9	231:10 282:5
197:5,16 199:8	8:11 10:25	353:24 354:12	pretty 27:12	291:17
202:18 203:6	19:10 29:21	practices 1:4	66:23	problematic
203:23 204:3	34:13,18 37:2	6:11 114:15	prevalence	224:18
204:18,21	37:2 40:13	precancerous	295:18	problems
207:17 223:24	41:3 80:4	240:14	prevent 47:5	146:11
239:25 269:7	117:3,24 124:7	precautionary	48:13 114:11	process 27:23
282:4 284:1,3	125:19 126:14	283:17,23	115:23 116:2	30:7 31:4,8,10

31:23 32:5	produced 10:8	326:8 327:17	283:9 319:12	121:14 122:16
35:11,14,25	10:13 14:23	328:7,15,16,17	profiles 169:20	167:25 177:2
36:18 37:1	17:19,24 19:8	328:24 330:23	progress 220:22	211:8 212:13
38:1 43:10	19:14,15 20:2	334:4	project 82:1,7	216:22 251:14
45:16 57:6,8	20:8 22:19,25	production 66:2	82:11	261:5,13
57:22 59:7	24:2 54:18	products 1:4	prominent	262:13,19
60:7 66:1	57:24 58:1	3:10 6:10 7:4	99:14	284:11 342:4
67:14 76:25	74:25 82:17	29:21 31:1,18	promoted 44:11	346:16 348:2,3
77:16,22 78:1	91:21 122:7	35:12 44:9,12	promotion 44:8	367:16
78:16 79:21	139:11 178:21	44:18 49:15	pronouncing	provides 338:23
83:7 92:5,7,7	190:3 195:23	51:6 52:16	16:15 289:21	providing 34:2
93:9 98:24	214:13 350:10	126:23 127:17	proper 83:13	44:12 45:10,12
104:14 105:11	produces 294:10	128:15 129:10	311:13	167:13 215:8
105:14 113:22	product 1:5 24:8	129:13,18,21	properly 42:16	347:25
115:14 116:11	24:14 29:22	130:5,14	properties	PTI 3:15,15 7:6
118:1,5,11	30:12 36:9	131:15 132:4	124:21 146:18	7:6
121:6 122:3	37:16 43:15	133:19 136:2,7	148:7 153:5	public 116:18
131:13 132:8	47:4,7 48:9,12	139:15 142:21	proposed	123:3,8 132:19
138:7 153:14	48:12,21 49:9	143:11,17	343:15	244:16 253:12
189:21 190:1,5	50:20 52:12,22	154:11,19	proposing 179:9	308:4 340:20
191:2,21	54:5 56:2	160:5,9 161:13	proposition	341:2,5,18
192:13 213:18	125:20 126:13	161:23 164:19	69:13	344:3,5,7
213:19 218:13	126:18 127:6,9	164:20,24	propounded	345:8 372:22
220:5,20,23	129:4 132:10	165:9,22 180:6	374:6	374:19
222:24 266:2	132:12,22	187:1 188:12	prospective	publication 76:2
279:3,6,10	137:9 138:4,14	189:18 198:2	79:17 239:8	77:15 116:13
281:14 292:2	144:4 145:8	200:3 202:21	protect 228:22	116:21 117:1
324:25 325:6	153:15,20	224:3 226:12	protected 23:23	210:19
325:13,23	154:5,15	226:16 227:1	54:4	publications
340:3 341:20	155:24 156:2	250:23 251:5	protective 1:9	107:23 117:5
343:6 345:21	157:20 158:15	255:24 256:21	228:4 232:23	publicly 30:22
348:25 353:6	158:18 162:12	258:5,8,17,19	prove 282:7	57:15 62:2
362:14	163:9,10,10	260:3 261:8	proven 285:18	90:25 118:2
processed 131:6	165:4 166:10	262:22 263:21	provide 18:3	121:22 286:21
processes 38:9	169:22,24	268:23 274:24	26:5 27:3	328:11 337:5
274:9 276:19	171:14,15,19	306:23 308:4	29:19 30:6,11	published 17:7,8
277:9	172:15 175:6	311:20 317:21	44:8 51:17	62:2,11 78:11
processing	178:4 179:4	318:10 319:6	87:3,10 122:9	91:21 92:1
130:22 131:10	197:7,9 198:23	322:16,18	213:20 214:21	93:14 103:9
132:16	199:14 202:25	324:4 325:9	263:17 322:14	108:7 117:10
PROCTOR	223:8 225:15	351:17 369:11	323:4,8 331:16	117:17,18
2:12	226:22 283:22	369:18,21	331:24 335:10	147:12 152:18
produce 44:11	285:23 310:12	Professional	369:20	162:10 163:14
140:19 168:25	311:8,15	4:24	provided 9:1	163:16 247:8
190:4 194:17	317:25 318:14	profile 39:13	10:3 21:10,11	248:25 249:1,4
196:1 242:15	318:14 324:10	86:21 150:24	50:21 55:20	249:21 250:12
272:18 326:16	324:18,20	254:7,10 283:8	85:21 89:15	286:17 314:4

321:12,17,22 publishes 343:11 346:11 pull 20:15 60:10 61:2 62:15 76:19 93:3,5 110:8 119:2,10 172:19 183:22 208:2,6,11 249:25 250:15 250:18 251:12 271:19,22 278:19 365:1 365:13,16 366:3,8 pulled 15:24 59:20 63:4 212:12,12 323:4 pulling 27:9 104:8 129:25 pure 142:4 222:7,16,18,20 222:21 223:21 purely 283:23 purities 139:6 purity 135:4 227:8 311:14 purport 278:13 purportedly 336:21 purpose 8:10 22:18 133:13 purposes 9:5 16:21 17:13 PURSUANT 1:9 put 22:5 26:13 26:16 51:7,7 58:21 62:8 78:14 80:16,25 83:13 136:17 179:4 193:11 198:24 218:10 224:10 231:22 246:6 247:11 271:7 281:7 307:5 347:11	355:23 puts 254:4 putting 118:3 135:10 138:21 197:13 254:5 puzzle 168:20 <hr/> Q qualified 355:13 357:11 qualitative 89:15,21,23 114:5 qualitatively 36:7 qualities 139:5 quality 88:3,4 88:16 91:1 92:22 207:10 232:3 quantification 36:13 157:21 170:16 310:24 quantified 298:9 quantify 36:6 77:2 86:4 88:13 168:12 168:13,15 171:2 172:13 172:22 187:13 237:24 243:9 298:8,11 quantifying 156:6 157:3,11 157:25 171:11 171:12,18,20 171:25 quantitative 78:12 85:21 114:6,11 115:24 205:15 207:19 queries 107:24 question 15:3 24:6 25:1 28:10,18 37:6 42:16 44:21	46:6 48:24 52:2 55:18,21 58:8 67:7 68:1 71:17 78:5 83:15 88:25 89:2 90:4 92:9 92:24 93:1,3 93:11,20 94:6 94:16,17 96:15 102:2 103:18 104:17 112:4 113:8 120:8 126:19 127:18 134:3,9,18 136:8 137:13 137:21 139:9 154:23 155:3 174:6 178:14 182:24 183:9 205:12 210:14 222:12 224:19 224:25 226:4 229:11,13,17 229:18 232:15 233:8 234:18 234:25 235:7 235:12 237:7 241:10 257:25 260:18 261:2 266:20 267:21 273:7,19,19 298:13 302:6 302:16 306:11 309:6 316:17 324:6 327:9,11 329:23 332:12 340:16 357:15 359:25 364:21 366:9,10,21 367:13 questioning 366:16 questions 8:2,15 13:19 16:18 17:11 22:10 23:19,21 24:10 24:19,23 25:2	25:14,17 28:16 29:15 32:14 33:11 39:14 40:3 43:1 45:7 49:4,24 50:16 51:15 53:3 56:14 59:4 67:7 73:12 74:9 75:6 87:1 88:19 90:2 91:6 93:10,24 95:2 96:17 100:1 106:8 107:7,21 111:6 111:24 113:24 118:23 121:19 127:13 130:8 131:24 133:3 134:8 135:19 137:2 139:7 140:3 142:11 144:1,20 145:15 146:1 155:11 156:20 158:11 160:1 161:3 162:20 164:6,15 166:1 167:15 171:16 174:4,13 176:8 180:1 181:9 183:11 185:15 187:11 188:8 190:22 193:21 196:3,18 199:15 201:1 201:21,24 204:10 211:16 215:14 217:16 218:16 221:23 223:23 232:6 234:5,19 238:19 239:6 241:4,9 242:6 253:15 255:21 259:11,20 260:24 262:1 263:4 270:23	275:9 279:8 280:7 282:14 284:5,24 286:15 287:9 287:15 292:10 293:10 296:13 297:12 298:15 299:23 300:19 303:11,17 304:17 306:14 307:18 308:1 308:10 309:7 310:1 312:1,6 312:13 315:13 315:20 317:1 319:2,4,14 322:9 323:1 325:15 326:21 329:7,19 330:12 333:1 336:4,5 337:11 340:24 343:10 348:19 351:14 352:6 354:4 356:19 357:10 358:12,21,23 359:5,11 364:20 368:20 369:5,12 370:17,22,23 374:6 quick 106:5,7 177:6 quickly 177:7 265:12 313:6 quite 37:25 70:8 79:22 130:12 196:11 298:24 300:6 319:20 quote 95:24 quote/unquote 70:15 142:7 175:10 <hr/> R R 2:1 3:19,19 rabbits 69:11
---	---	--	--	---

Confidential - Pursuant to Protective Order

Page 412

RAFFERTY	100:22 102:14	185:7 186:15	records 14:2	reflected 312:3
2:12	112:25 113:1,5	259:23 319:16	55:4 62:16,22	reflection 316:6
raised 314:9	120:15 137:14	320:5	62:25 136:14	322:23
raises 178:13	137:16,20	reasons 120:9	321:6	refresh 12:15
366:25	138:6 169:1	153:18 170:20	recovered	362:5
range 125:4	205:11 212:24	215:6	283:15	refreshed 15:16
128:25 129:5	236:14 251:3	recall 9:3 50:12	redo 74:20	refuse 24:22
173:13	284:9,16 316:3	51:14 120:21	reduce 252:12	regard 84:16
ranges 125:3	337:22,23,24	162:17 174:22	252:19 292:18	123:3 295:19
rank 100:25	338:3,3,5,6	206:9 207:15	reevaluate	306:4 318:18
101:2 197:22	349:12 367:10	208:3,11 250:1	246:15	regarding 252:7
ranked 256:18	367:11 373:3	263:1,3 265:6	refer 13:7 16:13	321:9 332:4
ranking 101:22	374:4	278:24 280:21	21:21 22:13	339:17 342:21
103:24 113:18	reading 52:18	288:5 319:8	35:13 131:8	344:22 345:18
114:2,22	59:18 60:2,11	347:6 368:16	161:22 202:9	361:15
rankings 107:6	81:2 183:7	369:12	250:19 349:18	regardless 71:20
114:18 115:9	243:25 314:25	receipt 373:15	reference 9:16	140:14 145:8
134:4 141:8	315:2	receive 346:10	22:5 46:20,22	153:4 159:18
rate 265:11	reads 47:3	351:16	49:1 64:11	181:6 258:10
ratings 218:22	212:18	received 122:4	75:9 76:10	258:23 273:21
rats 271:13	ready 13:10	recognize 8:19	93:13 118:19	289:8
raw 307:21	308:13	61:3 111:11	158:12 263:14	Registered 1:17
reach 76:4 180:7	real 54:15 62:7	128:18 140:8	280:18 337:12	372:3,18
186:8	106:5 177:6	226:24 270:10	referenced	regularly
reached 95:25	realize 60:11	recognized	12:23 15:3	296:15
181:11 189:7	really 37:12	220:17	46:9 91:17	regulation 43:12
189:14 190:10	57:24 59:20	recognizing	167:24	46:10,18 48:17
190:24 191:20	98:15 106:6	138:2	references 63:18	49:1
192:8,15	129:10 154:25	recollection	64:8 218:25	regulations
198:11 236:17	195:15 225:10	362:12	referencing	30:10 43:5,7,9
reaches 96:4	225:11 232:2	recommendat...	318:17	44:2,14,24
reaching 75:16	289:2 298:16	283:22	referring 13:6	46:17 48:4
89:6 160:2	333:2 347:23	record 6:2 9:6	15:12 22:14	327:10 328:20
186:20 208:22	355:20 356:23	10:15 16:21	43:8 64:1,2,22	regulator 214:3
258:13 261:3	356:23	17:13 19:23	89:10 116:8	regulators 31:16
reaction 140:17	realm 24:9	25:7,10,11,13	148:11 161:15	32:2 219:21
233:2	Realtime 1:18	55:8,9,20,22	201:16,18,19	regulatory 30:7
reactions 140:16	372:3,18	56:12 94:21,23	201:22 205:14	30:13 31:23
179:18 243:18	reason 73:1	94:24 95:1	206:5 238:17	43:18,22 47:23
reactive 150:10	97:10,13 98:1	99:22,23,25	242:17 309:18	65:5 67:11
read 32:22 34:9	202:23 212:12	111:8 188:2,4	321:11 341:5	81:21 82:8
34:16 59:14,17	245:21 281:3	188:5,7 200:20	360:9 362:8	213:6,8,11,25
59:21 60:1,22	347:22 354:5	200:22,23,25	refers 64:22	214:3 219:17
64:10,12 71:23	366:10,15	287:4,5,7	202:4 214:8	256:6,19 284:2
77:21 80:9,13	373:5	364:9,13,16,17	refine 81:24	290:13 307:19
81:12 83:21	reasonable 41:2	364:19 368:25	82:4	322:17 323:20
90:16,17	157:23 173:17	369:1,3 371:2	reflect 20:14	324:3,25 325:6

325:13 326:4	241:18 294:13	313:23,24	repair 283:15	102:10,22
326:13 331:12	295:17 365:21	reliably 42:9	repeat 12:20	104:21 113:10
332:14 333:5	370:13	232:14 291:22	365:8	118:14,15,19
333:10,21	relative 146:4	reliance 20:24	repeated 198:25	118:22 119:13
334:8,8 335:4	152:14 372:11	21:18 22:1,8	199:17 300:24	119:15 121:18
335:9,24 367:2	372:12	55:10,13 59:13	302:20 305:11	122:8,13
relate 11:21	relatively	59:25 60:1,15	repeatedly	123:11,12,24
19:11 28:20,22	319:13	60:20 63:5,12	339:16	124:12 133:8
29:2,3 46:17	relevance 70:16	63:13,21 64:1	repetition 87:24	133:22 134:10
52:25 76:20	84:22 92:8	64:6 68:14,22	rephrase 161:18	138:6 139:11
101:14 126:22	153:8,10	83:2 108:16,21	replicate 58:4	140:22 141:20
127:3,3 129:19	207:10 218:1	108:22 109:2,4	58:10 98:23	142:20 143:6
133:9 137:5,8	231:7 232:13	120:15 122:7	replicated 47:2	146:3 147:5,9
139:15 140:23	relevancy 118:4	211:9 212:1	75:11	154:3,4 155:13
140:25 162:24	relevant 36:3	241:15 263:8	report 4:13,14	158:16,21
178:17 211:7	54:7 60:2,12	263:10,13	4:16 12:15	159:1 169:1
212:6 250:13	69:17,23 71:16	relied 70:19	13:8 14:7,15	176:11 182:16
322:16 324:12	76:8 78:4	74:3 109:6	14:21 15:5	183:2,7 185:3
351:3 355:17	80:16 83:10,15	130:1 162:23	16:4,9,10 17:3	187:10 188:15
related 8:11	96:7 97:1,8	174:24 214:23	19:13,21 20:2	189:14 201:9
10:6,25 29:19	101:24 123:1,1	215:4,9 238:24	20:8,17,19,23	209:22 214:12
30:9,20 31:17	127:4,11,16	relies 336:17	21:2,16,24,25	214:21 215:3
50:20 68:5	131:15 135:17	rely 41:5,5	22:4,9,20,25	236:2,25
123:11 125:17	138:9 141:11	105:22 156:23	23:4,7,8,12	241:14 242:8
134:12 135:21	150:24 153:12	160:8 205:7	24:2,12,19,24	243:25 256:25
165:20 207:3	182:17 202:22	207:18 212:11	25:19,21 26:2	261:18 262:20
255:15 259:16	206:24 207:5	247:23 277:20	26:24 28:25	263:6 266:8,21
265:2 318:9	212:8 216:5,11	337:7,16 360:6	29:12 30:17	267:3,8,12,22
322:14 323:9	225:21 234:17	relying 45:4	32:7,10,11,21	268:9 269:8
323:20 324:14	258:3 271:11	143:5 338:25	32:24 34:8,9	274:18,20
332:6 342:19	314:8 324:5	remain 265:16	34:16 46:21	275:3,11 277:1
relates 77:7	351:16 366:7	remember	53:6 54:23	280:18 285:20
127:11 132:18	reliability 66:16	242:13 259:15	55:11 56:17,24	288:2 289:17
143:2 149:1	67:19 83:11	317:11 327:23	59:6 61:9,15	290:8 295:22
155:9,15	84:21 118:4	362:7 368:12	63:11,17,20	309:11 310:4
255:14 258:1	207:10 208:17	remove 45:17	64:14,16 65:14	313:13 314:25
relating 253:9	209:1,11,24	65:23 67:21	65:25 66:3,11	315:3,8,19,23
relation 365:7	210:7,13	268:5	66:22 67:8,24	316:4 317:7
relationship	215:17,21	removed 109:13	68:3,14,18,23	322:25 323:3
27:25 34:3	216:7 218:1	removing 268:7	74:18,22,24	326:11 331:14
110:7 112:7	247:20	render 37:21,22	75:20 76:12	332:22 333:16
193:17 202:11	reliable 42:8	39:19	80:20,23 81:10	336:11 337:7
204:15 207:21	66:20 83:9	rendered 144:6	82:17 83:1,21	337:13,17,20
230:16 235:13	95:7 209:9	237:1 262:3	84:1 86:3 90:8	337:22 338:2
235:24 236:11	210:20 216:6	286:2	91:22 93:15	338:11,21,22
236:18 237:3,6	216:11 231:2	rendering	95:11 99:14	339:9,21 340:2
238:9 241:16	232:17 305:25	216:21	100:3,12 102:3	340:9,17

343:18,23	18:10 26:14	respective 80:7	results 113:3	79:24 80:6
347:3,21 361:7	requested	respiratory	184:13 334:17	82:20 90:6
361:15,24	322:11	126:6 129:12	retained 248:3	108:13 110:4
362:10,20	requests 17:17	respond 228:10	365:23 367:2	116:9,16
363:23 365:11	17:23	228:10,12	retention 346:8	120:20 122:13
reported 42:7	required 30:10	233:21 234:2	361:9	129:17,19
87:20 117:23	37:21 43:4	responded	retrieval 25:24	151:8 163:24
160:16 170:14	219:18 324:10	363:13	63:1	177:12 183:14
177:22 178:16	326:16	response 9:24	retrieve 25:23	201:8 243:20
183:20 267:4	requirement	76:15 77:5,7	26:6,21 27:18	252:2,4 323:24
295:3 310:14	49:8 114:22	78:7 90:3	retrieved 26:4	342:18 344:10
310:22 328:12	requirements	126:2 128:17	60:17,17 207:9	347:12 356:14
reporter 1:17,18	114:23 322:17	128:19 150:10	retrieves 26:14	356:22
1:19,20 7:17	324:3	169:1 179:14	Retrograde 69:9	reviewing 31:17
137:20 372:3,4	requiring	187:8 190:13	return 74:12	58:2 81:19
372:4,18,18,19	279:10	194:12,16	373:13	82:19 133:1
372:20,20,21	research 107:12	195:20 204:2	returning 17:16	208:21 343:2
372:22	resource 290:6	223:22 225:2	96:24 118:12	reviews 81:21
reports 12:6,7	resources	228:1 230:22	219:23	82:2 98:14
12:25 13:5,15	214:23	232:19 237:17	Reuters 123:12	280:13 321:14
13:21 19:8,11	respect 17:20	237:19,21,25	123:16	348:8,11
27:25 28:20	28:3 31:7,8	238:1 239:16	revealed 261:21	revisit 182:6
29:13 33:16	43:3,25 44:2,5	240:10,13,20	review 4:18 26:1	rgolomb@gol...
57:23 61:11,17	44:25 48:20	240:24 241:23	30:23 32:19	2:17
63:10 68:11	53:12 62:17	242:4 254:14	53:12 56:20	Richard 2:17
74:20 75:9	69:2 70:5 80:4	266:9,12	57:6 59:8 61:7	7:1
85:15 178:5	106:1,3 109:17	293:25 364:24	63:5 65:5	right 8:3,4,25
179:5 248:1	110:6 112:7	365:3	67:11 71:15	9:14 10:12
249:6 257:2	117:23 125:12	responses 72:21	78:1 82:8,15	12:2,22 15:2
261:6,12,22	127:21,23	195:23 238:2,6	82:22,24 83:5	16:19 17:12
314:15 337:20	128:7 129:21	242:23 266:5	85:4 98:11	18:18 19:7,20
represent	144:6 151:17	272:14 273:24	111:25 116:11	20:1 21:17
287:18 319:6	151:21 157:5	responsibilities	121:16 156:24	23:2,5 34:22
representative	162:25 165:10	332:5	160:12 182:8	40:10 41:25
133:20	170:7 171:2,18	responsibility	184:2 208:8	46:20 47:1,14
representing	172:14 173:20	360:15,18	209:13 211:9	59:12 63:13
22:15	179:11 192:16	responsive	216:8 245:5	67:24,25 69:24
reproductive	196:21 198:3	17:22	297:8 321:5	82:5 89:14
70:11 71:18	202:10 204:13	rest 281:20	336:6 338:9	95:3 96:23,24
95:20 101:11	204:15 212:7	restate 190:19	341:9,20	102:1 107:11
101:15 103:11	256:22,23	result 98:2	342:15 343:12	108:1,5 109:15
103:12 183:16	262:18,22	119:15 132:9	343:13 348:1	111:25 112:19
184:4 297:18	263:15 272:3	153:8 169:14	348:14,15,18	113:2 119:11
302:10	282:18 283:22	170:17,17	349:2 368:12	124:11 126:16
reputable	284:7	194:19 198:18	reviewed 9:21	133:6 134:6
353:15,20	respectfully	213:22 272:20	12:6,24 21:3	178:24,25
request 9:17,24	139:8	304:21	32:13 67:5	188:22 198:14

204:9 205:25	157:19,25	301:20 306:18	106:22 114:17	sampling 170:14
206:10,13	158:4,14	306:24 314:12	183:5,15,18	186:1
207:8 208:13	159:17 160:3	314:14,16	187:4 227:25	San 3:4
211:17,19	165:8,14,21	319:18 321:1	283:10 300:8	Sanchez 261:7
236:16 243:15	167:5 168:13	323:19 324:16	300:10,21	261:18 262:20
245:12 263:15	169:3,23	324:22 326:15	301:7 302:25	sat 74:21
276:8 283:20	170:21 171:2,8	326:18 327:21	342:8	save 80:12
306:15 318:6	171:13,13,18	329:25 330:9	Rowlands 250:4	saved 56:9
320:13,17	172:2,10,13	330:18,20	Royston 3:15	saw 179:18
323:13 324:7	173:1,3,5,7,12	331:3,5,25	7:6	259:15
330:15 331:9	173:19 174:8,8	332:7,20	rsullivan@dy...	saying 45:4
333:8 336:9	188:13 191:25	333:14 334:3,4	3:3	106:9 123:13
338:14 339:22	197:13 198:1,4	334:16 335:17	rule 4:16 305:17	143:23 149:3,4
341:10 344:3	198:5,22 199:9	357:6 369:21	rules 106:17	150:12 158:2
344:17 345:8	199:12,13	risks 143:20	Ryan 2:4 3:2	159:10 173:24
349:12,14	200:4 201:14	154:17 275:24	6:22 7:8	193:9 203:23
352:17 359:13	202:3,18 203:6	351:8	Ryan.Beattie...	213:17,18
360:24 363:3	203:12,23,24	Risperdal 246:4	2:5	224:8 227:23
369:6,14	203:25 204:11	road 2:9 220:19		231:12 240:5
ring 206:5	204:18,21,22	222:25	S	251:8 256:11
risk 4:20,21	205:8,11,13,23	robust 128:19	S 2:1	262:15 273:3,6
16:12 17:8	206:20 208:23	robustness 88:2	sac 101:19	274:14 281:12
34:18 35:5,11	212:20 213:8	Rohl 250:3	sacrifices 231:1	304:20,20,24
35:24 36:6,8	214:1 216:3	role 29:10,14,17	Saed 313:21	316:19 334:14
36:11,12,13,17	229:20 231:3	33:20,20 75:14	314:4 315:2	338:8,15
36:20 37:10,15	234:17,23	99:14 124:1	safe 117:15	356:20 357:13
37:19,23 38:2	235:4,22 236:2	125:10 127:20	294:22 328:18	357:14,19
38:3,10,17	236:12,19	246:15 255:22	328:24 347:18	366:16
39:3,10,17,20	237:4,23,23	268:25 306:1	safety 30:12,21	says 7:23 104:10
40:13,23 41:4	239:18,21	331:19	31:5 35:13	109:20 110:21
74:11 75:21,25	244:20,24	roles 334:22	36:21 49:21	129:24 191:11
76:9,24 77:2	255:25 256:8	route 52:24	53:1 75:22	191:15 250:2
80:3 85:1,2	256:22 257:6,9	231:12 258:3	97:17 99:17	361:23 365:4
88:13,18 107:3	264:8 266:4	269:25 292:5	324:10,11,17	scenarios
110:18 111:2	268:18,20	347:19	324:20 328:6	179:24
112:23 115:7	269:1 271:12	routes 233:11	328:10,15	Schedule 9:18
115:13,17,21	272:7,19,21	routine 115:8	329:17 331:1	9:21,25 17:18
117:5,13,13,19	273:5 274:14	178:3 184:7	346:12 347:16	17:23
122:23,24	274:25 275:7	200:13,15	355:20 360:7	schools 290:13
123:5 124:6	275:20,24	207:25 282:25	sake 111:8	science 31:14,15
125:12 127:12	278:8 283:3,8	283:3 284:15	Sales 1:4 6:10	31:17 105:16
138:7 141:21	283:9 285:7,22	296:16 299:20	sample 129:4	191:11 192:9
143:16 146:16	286:11,23	301:1,6,10,25	131:5 170:12	274:6
149:19 150:7	289:10 291:2,3	302:17,17	252:10	sciences 356:2
153:11 154:24	292:15,18	305:11 307:3	samples 151:4	scientific 41:2
155:2 156:7,10	293:7 294:20	307:10 346:3	163:21 179:20	62:18 65:5
157:3,12,13,15	294:24 295:12	routinely 106:21	223:11 247:25	67:11 76:10

80:6 81:12	58:4 61:14,23	235:23 240:25	select 129:6,6	217:14 218:14
96:7 97:2,8	62:17,19	249:14,22	130:4	serial 231:5
98:13 99:4	searching 54:12	254:2 261:24	selecting 141:13	series 220:16
121:23 122:22	54:20	265:19 267:6	selection 130:13	232:8 246:5
124:9 134:22	season 301:7	267:19 268:3	sell 308:4	serpentine
173:18 182:8	Seasons 1:14	270:17,18	selling 316:20	255:6
183:1 185:8	second 23:15	279:11 284:21	317:19,24	served 33:21
186:16 190:10	24:5 52:6 69:7	297:23 316:19	318:2	serves 246:20
190:24 192:15	188:2 273:18	318:16 337:14	Seminary 2:9	service 26:8
205:16 209:25	324:2	341:9 353:25	sense 40:19	Services 1:21
210:8 245:1	second-guess	365:18	182:6 195:17	3:20 6:5
259:23,24	198:10	seeing 63:19	195:19 285:11	set 29:8,11
272:1 273:8,10	section 16:3	170:24 270:9	285:25 332:25	30:17 31:4,21
275:14 276:9	66:25 100:20	367:20	sensitivity 223:6	36:14 55:23
278:10 282:16	105:2 112:10	seeks 359:22	sensitizer	56:19 75:1
321:6 324:5	112:13,20	360:2,6	276:20	84:24 106:16
326:23 329:22	123:25 124:1,2	seen 8:22 21:7	sent 63:21	117:14 146:7
333:5,7,8	126:21 133:7	42:6 48:3	sentence 47:11	180:3 188:18
334:10 359:23	139:21 140:6	78:18 85:14	47:15 64:21	210:16 220:5
360:3,12,19	179:2 188:15	106:20,22	65:3,19 66:10	304:1 311:10
scientifically	206:23 212:5	107:1 110:14	67:8 112:20	311:15 372:9
30:8	212:17 215:7	110:15 111:22	147:11 212:17	setting 11:20
scientist 77:22	333:16	115:1 123:18	236:23 243:10	23:24 35:25
191:8 320:5	sections 30:15	129:23 130:1,9	251:3 267:12	148:20 174:21
scientists 84:13	30:17 326:10	148:12,21	317:4,6 339:14	175:2 176:13
99:10 104:15	see 9:11,19	149:21 151:1	366:6	176:22 222:25
105:12 107:4	16:19 18:11	153:4 154:10	sentences 65:21	273:25
114:16,17,18	20:10 30:16	161:6 170:13	separate 30:4	settle 182:24
319:17,22	34:8 39:18	176:12,13	48:4 63:12,21	settled 182:25
321:18 322:2	47:1,8,17	177:13 187:13	64:4,5,7 124:8	seven 88:21
scope 117:8	51:12 64:21	205:14,21	139:5 177:1	316:4
scoring 206:1	65:1,7,11,18	207:14 211:13	201:13 202:4,5	SEYFARTH 3:7
207:11,19	66:20 79:2	211:23 225:17	208:24 215:24	shape 127:25
208:4	87:10,24	225:19 228:20	217:9,18 224:4	sharded-type
screen 92:8	102:18 110:21	241:24 248:7	244:21 251:22	255:1
screening 209:5	115:3,3 123:22	248:16 252:6	260:10 263:23	share 146:18
se 124:10	134:2 136:6	259:12 260:9	285:7 289:13	154:12 160:17
search 26:12	147:17 149:24	261:17,25	318:14 323:20	161:5,9 233:17
27:4,19 53:18	151:3 154:2	262:2 263:10	324:17 325:14	272:19 278:22
59:10 62:4,7	156:5 159:16	270:25 288:21	325:24 326:10	370:10
90:24 121:11	163:14 166:25	299:13 306:22	329:23 333:16	sharp 254:25,25
206:24	177:7,10,21	309:12 311:19	333:21,22,25	SHAW 3:7
searched 338:13	188:16 199:24	312:2 313:11	separated 210:8	sheet 373:6,9,11
searches 25:22	203:2 205:19	321:8 342:14	215:19 217:4	373:14 374:7
26:20 53:11,16	206:22 207:1	361:1 362:13	separately 12:1	Shifting 307:19
54:6,12,17	207:12,13	segregate 59:1	13:11 330:21	Shimmer
55:5,23 57:5	208:18 214:10	145:12	separating	126:17 157:5

161:14 308:20 short 12:9 348:11 368:21 shorter 306:13 Shorthand 1:19 372:4,19,20,21 shot 28:18 show 103:8 150:4 159:16 172:8 206:4 221:21 229:19 238:9 244:9 246:8 250:9 257:15 270:5 276:9 280:2 301:15 305:19 showed 177:2 183:25 SHOWER 126:14,14 157:4,4 161:14 161:14 308:20 308:20 showing 42:7 68:5 103:8 157:17 172:24 184:10 221:18 237:22 274:21 shown 41:23 70:22 153:6 242:15 251:7 256:9 257:11 257:19 260:15 271:11 272:18 279:5,16,17 281:18 shows 36:7 41:10 70:9 71:5 103:13 145:7 151:1 158:13 169:24 199:10 245:6 302:23 sick 178:23 side 335:23 sides 248:15 sign 373:8	signal 173:12 significance 40:6 41:24 42:14,23 92:20 significant 33:17 41:8 42:11,12 91:3 133:5 157:18 172:24 257:16 313:2 357:5 signing 373:9 signs 238:11 silica 264:18,20 264:20 similar 54:21 70:4,12 71:2 71:24 79:23 117:7 118:11 144:23 145:2 153:15 169:25 231:24 233:17 243:21 254:6 268:10 272:20 273:23 275:22 276:18 289:7 similarities 233:4 234:8 simple 36:11 264:16 simply 26:5 38:16 67:8 89:2 93:12 106:9 110:3 113:9 139:2 144:2 241:12 294:11 306:3 single 242:14,21 243:2,14,16,17 283:1 298:18 368:9 sit 34:10,23 51:16 60:21 74:16 110:23 119:11 120:22 145:16 162:21 176:1 188:9 202:6 245:12	250:11,18 259:21 276:24 278:9 280:23 368:18 site 64:24 180:21 242:16 243:18 264:23 281:16 295:4 sitting 18:16 368:15 situation 96:11 96:18 97:22 246:2 273:25 297:6 326:5 342:11 situations 246:1 361:1 six 18:20,21 97:24 98:1,5 172:5 249:10 266:25 267:17 301:3 316:4 size 92:23 124:20 125:3,4 125:7,10,15,23 127:19,25 128:7,8 129:6 129:21 150:11 sizes 124:24 128:14 129:5 230:23 skin 271:21 slightly 46:6 55:18 65:20 small 129:10 202:14 243:12 smaller 125:4 126:2 129:6,14 177:21 Smith 2:22 7:12 7:12 42:18 257:14 Society 355:3 sold 48:13 138:15 251:6 253:10 308:13 316:15 325:10	solely 351:17 solicit 340:23 soliciting 342:2 solicits 340:19 solubilized 72:8 264:11,17 265:23 soluble 72:12 somebody 173:25 225:19 246:10 283:10 305:18 318:3 320:19 335:25 357:3,4,17,21 somewhat 265:2 313:3 sorry 11:8 12:21 19:6 137:13 226:20 257:14 267:11 269:10 274:4 289:23 289:25 298:12 310:2 313:14 313:15 333:3 339:5 345:13 355:23,24 358:25 360:1 363:5 365:8 367:8 sort 15:14 30:1 30:2 37:13 85:21 178:9 235:17 299:20 332:1 351:10 sound 323:7,13 sounds 96:23 322:22 source 133:11 136:10,15 216:11 251:21 336:12,17 337:1 339:17 339:25 340:1 349:16 sourced 318:13 sources 130:16 136:21 137:6	139:13 144:17 162:18 167:7 266:17 313:23 sourcing 137:1 South 2:14,23 3:13 space 180:11,13 373:6 specialist 47:24 species 68:6 182:20 specific 12:24 15:4 22:20 29:5 39:25 50:4 51:1,21 56:19 71:9 76:22 82:21 91:10 93:2 103:17 105:4 109:22 110:9 116:10 123:10 123:10 124:18 125:15 129:18 141:21 147:24 148:15 159:4 164:3 166:17 168:1 172:3 174:11 185:13 189:16 202:16 202:19 210:16 210:23 211:2 212:22 214:14 218:21 224:10 224:20 250:24 253:4 259:6 275:6 277:2 282:21 304:2 310:19 321:12 345:5 349:1 354:1 355:16 357:22 368:17 specifically 11:22 15:8 21:23 22:8,19 22:25 43:8 46:22,23 50:13 69:21 77:12
---	---	---	--	---

91:13 97:10	57:10 60:11	365:3	streams 27:8	154:14 155:1
100:6 102:2	62:10 80:19	statements 17:6	Street 1:14 2:5	155:10,23
113:13 118:21	81:21 82:1,11	35:20 74:5	2:14,18,23 3:3	156:1,25 158:8
119:23 125:9	90:23 93:19	110:12 191:18	3:8,13	158:9,17,22
135:2 151:20	127:24 128:7	193:11,16	strength 38:13	159:3,9,16,18
153:22 154:4	189:11 216:25	202:17 336:7	38:22,23 39:4	160:7,7 163:16
154:18 158:17	248:24,24	351:3	strengths	172:25 173:13
160:7 163:9	298:13 326:16	states 1:1 6:11	102:15	174:23 175:10
189:12,17	365:7	47:15 49:13	stress 227:13	175:16,19
196:2 201:18	started 8:5	65:4 67:9	228:2,6 277:8	177:18,22
214:8 227:11	19:25 32:5,17	112:21 207:8	278:23 279:2,7	178:4 183:14
244:12 249:17	32:23 54:12	322:19	stressors 228:23	183:22 184:9
258:1 264:7	59:18 60:2	stating 134:25	stretched 297:2	185:24 187:7
265:4 272:4	74:17 95:4	204:14 243:11	stronger 203:9	187:20 205:17
285:2 350:13	163:7 323:8	statistical 40:1,5	203:20 204:18	206:25 207:6,9
354:21 355:25	329:13 331:11	41:8,24 42:13	structure 59:11	207:20 208:4,5
specification	331:12	42:22 92:19	124:20 125:11	208:16,21
311:11	starting 15:13	209:13 218:2	125:16,23	210:8,12
specifications	102:19 138:25	statistically 91:2	127:19 255:1	215:16,20
129:20 165:3	starts 35:25	92:19 157:18	studied 70:22	216:7,10 217:6
311:15	state 53:8 70:8	158:14 172:24	159:5 255:18	217:7,9,10,22
speed 73:11	84:5 95:17,23	statistics 92:20	269:23,24	217:25 218:3
spent 10:23	135:4 147:12	stay 220:21	studies 41:20,21	222:15,17
11:13,18,20	164:1 173:6	337:13 364:12	41:22 68:2,5,9	223:11,19
12:1	183:2 190:20	steering 340:6	69:13 73:22	224:13,21
spoken 345:4	236:6 242:12	340:10,14	74:6 81:19	225:17 228:14
sponsored 247:9	284:20 286:18	Steinberg	83:12,25 84:6	228:20 229:15
St 1:14 3:14 6:9	293:16 340:2	344:11	87:25 91:2	230:17,18
19:19 20:21	340:18 373:5	stenographica...	95:18 96:20	234:9 237:20
stages 272:13,15	stated 28:3	372:8	97:24 98:6	237:21 238:7,9
341:23	34:20 109:16	step 36:2 139:21	99:1 100:2,5,9	238:23 239:4,4
stakeholders	112:5 183:13	139:25 188:23	100:25 101:4	239:8,18 240:8
344:8	208:1 251:10	189:23 235:14	101:24,25	240:9,9,12,16
standard 49:20	298:24 344:24	235:22 279:1	102:5,7,16	240:17,18,22
116:4 185:10	statement 36:10	332:24	104:5,18,22	241:13,17,25
186:17 285:18	42:9 47:4	steps 75:25	105:19 106:4	242:20 243:24
324:19 326:14	48:15 52:18	76:13 77:3,4	106:19 113:4	245:17 246:16
327:11 328:2,3	110:9,25 173:3	sticky 218:10	114:8,22 115:5	274:18,21
standards 38:7	192:3,5 199:4	stilled 243:1	115:5,9 117:10	275:14 276:9
starch 69:10,25	202:5 204:22	stimulate	119:18,21	277:19,21
70:1 71:2,6,10	211:2 213:5	273:23	120:4,25 127:8	285:3,6 288:21
71:23 72:6,7	230:9 240:2	stomach 271:13	133:24 138:16	291:18 293:17
72:13 73:7	243:22 250:20	stop 82:11 334:5	140:23,24	295:20,21
93:4,7 265:10	253:7 284:12	stopped 331:7	141:21,23	296:9 302:24
265:16,22	284:14 318:7	stopping 116:3	142:3,4,5,6,19	310:6 312:2,8
266:19	338:24 347:16	story 178:9	143:13 145:12	312:8 313:8
start 8:16 31:25	349:25 350:3	strategy 58:12	152:17 154:4	314:10,15,18

314:19 315:14 357:7,23 358:1 study 36:19 42:14,15 69:3 69:20 73:4,14 73:20 79:17 84:9 87:19 88:4,8,8,14,16 89:25 92:17,22 96:4 99:2 102:13,14,24 104:4,10,11,25 114:7,10 118:15,25 119:8 120:2 134:12 145:10 152:12 155:9 155:15,16 156:17 159:19 160:12,23 170:17 172:18 175:13,17 182:19 206:18 207:18 209:14 209:20 210:24 211:3 216:1 217:20 218:2 220:11,24 222:19,22 223:17 224:5 225:18,20 228:17 229:9 229:10,22 230:22 231:1,4 232:2,3 233:1 235:10,19 239:20 241:2,3 241:8 244:3,5 244:8 246:19 291:8,21,25 292:1,13 297:21,24 298:1 312:16 studying 73:25 subject 43:12 287:10 373:10 subjects 100:7	submission 364:25 submissions 362:6 submit 341:15 341:19 343:7 343:17,22 345:17 368:7 submitted 10:16 10:20 116:13 116:21,25 342:21 344:1 361:14 363:2 363:11,15 submitting 361:24 Subscribed 374:15 subsidiaries 44:20 substance 35:4 40:12 103:14 147:23 374:7 substances 70:21 72:22 105:5 256:3 substantial 226:15 258:5,9 substantive 26:24 substituted 174:6 successfully 182:12 suffice 43:20 sufficient 40:15 276:6 306:8 326:2 suggest 281:24 suggested 51:20 313:8 suggesting 114:7 284:13 suggests 195:2 Suite 2:9,14,18 3:3,13 Sullivan 3:2 7:8	7:8 summarized 202:14 summary 83:18 summer 20:11 21:5 supplemental 4:14 14:14 20:2,8,17,19 23:4,8 32:10 266:21 267:3 supplementary 208:2,9 supplied 204:12 supplier 307:21 307:25 308:2 309:4 supplies 308:11 supplying 317:9 support 21:21 22:9 112:18,22 139:14 338:23 350:14 supported 184:8 supporting 37:11 48:17 307:2 supportive 337:20 supports 194:11 sure 19:17 24:7 27:21 56:4 63:8 78:24 109:12 120:23 121:5 123:17 177:9 242:10 269:14 271:21 278:13 281:11 287:13 308:25 316:5 323:10 323:12 364:11 367:5 surety 121:8 surface 180:14 180:19 264:22 329:4 surprise 345:1,3	surprised 79:22 survey 139:2 susceptible 292:1 suspended 177:14 suspicion 366:25 sustained 140:17 swear 7:18 sworn 7:21 372:5 374:15 system 26:10 87:15 90:4,9 90:14 91:10,13 91:18 92:6 113:18 206:2 207:11,19 276:21 335:9 Systematic 4:18 systematically 264:12 <hr/> T T 3:7 T-a-h-e-r 16:14 table 79:19 86:4 87:12 89:11 203:18 Taher 4:20 16:14 201:23 205:8,13 206:18 215:16 take 28:17 36:12 70:23 94:19 103:4 128:7 131:22 160:15 188:22 197:19 203:18 208:13 223:7,15,16 228:21 243:23 246:18 287:2 taken 110:6 131:11 218:9 299:10 368:6 372:8	takes 26:13 102:11,12 talc 3:5 4:19 15:16 17:6 29:25,25 30:21 31:5 57:22 62:8 64:23 65:6 66:5 67:9 67:12,16 68:6 69:14,18,21,24 70:12 71:3,11 71:19,24 72:6 72:11,19 73:8 73:15,25 74:7 77:10,10 86:21 93:7 95:19 97:17 100:6 108:8 109:18 110:7,13,25 112:7,12,20,23 119:5 124:14 124:20 125:3 125:11 126:22 127:19 128:8 129:4,13 130:4 130:16,18,23 131:14 132:3 133:9,10 134:13,14 135:2,3,14,22 135:25 136:11 136:15 137:5,6 137:8 138:10 138:18 139:4 139:13,14 140:24,25 142:2,3,4,7,13 142:15,21 143:1,3,20 144:17,22 145:18,20 146:5 147:1,3 147:14,14,15 147:15,20 148:13,24,25 148:25 149:13 149:14,16,18
---	--	--	--	--

Confidential - Pursuant to Protective Order

Page 420

149:18,21,23	259:2 260:11	369:11,17,21	128:12 153:21	tell 7:22 12:17
149:24 151:2	260:11,16	talk 13:9,9	156:12 167:12	52:4 53:2 59:3
151:19 152:24	261:5 262:9,19	31:11 34:4,16	167:21,22	60:25 68:25
153:5 155:16	263:16 265:10	75:21 77:19	168:6 175:22	76:19 78:24
159:4 161:11	265:15,24	79:15,17 85:2	177:25 202:1	100:21 101:9
161:12,20,23	266:5,10,19	100:20 101:4	203:11 209:11	101:22 102:8
162:14,18,25	267:5 272:20	107:1 112:12	216:2 223:25	109:20 119:8
163:18 164:8	273:1,1 274:15	119:1 123:7	238:15,18	121:7 123:25
164:17 174:18	277:12,24	124:19 128:25	240:3 248:8	129:24 136:16
174:20 175:14	278:13 280:24	138:11 146:11	262:9 270:20	139:19 141:17
177:14,17	281:17,23	146:14,25	270:21 281:15	153:2 155:20
178:15 179:11	282:18 283:9	147:2 149:13	291:10,13	169:18 182:15
180:4,6 181:12	285:22 286:18	149:22 150:17	294:4 302:17	188:17 191:9
181:19 182:13	286:22 291:6	153:11 161:8	302:19 305:6	192:19,20
183:3 184:12	293:15,20	162:18 164:24	306:16 309:21	193:10 200:9
184:13,19,22	296:14 297:16	166:2,3,5	309:22 310:3	201:11 236:22
185:10,18,20	297:24 298:4,5	184:2 192:4	329:13,20	245:12 249:10
186:7,19	298:18,19	194:1 201:5	330:5 333:4	251:2,11
187:14,17	301:13 302:8,9	208:6 209:11	334:15 338:14	262:25 300:13
188:12,25	305:21 306:5	219:6,21	348:5,8 351:7	305:3 307:7
189:1,17 190:3	306:23 308:23	221:13 252:21	361:12,17	314:25 316:2
190:4,11,25	310:7 316:14	264:6 266:17	362:10 365:19	316:10 339:24
191:13 193:3	317:9,19,25	269:4 272:11	367:24	telling 52:7,15
193:18 195:24	318:2 319:18	272:12 277:11	talks 17:5 71:5	105:1 138:9
196:6,20 197:2	320:12 321:1	282:24 283:4,6	72:17 73:5	172:4 186:14
198:21 202:11	322:5 324:6,13	285:16 311:4	103:10,13	210:3 284:21
202:18 203:1,6	324:23 325:1	333:13,17	128:24 139:3	309:2 315:13
203:21 204:16	325:17 326:23	335:2,8,11,19	149:14,15	tells 62:23 83:5
207:21 208:23	327:5 329:25	340:12 347:3	202:17 208:15	232:6 265:19
221:24 222:7	331:5 332:6	347:17 352:19	292:12 296:5	302:13
222:16,19,21	335:12,13,14	359:20 370:2	365:12	ten 11:11,18
222:21 223:12	341:16 342:12	talked 43:2 88:5	tangent 330:7	183:23,24
223:13,20,21	342:21 344:16	95:14 138:21	target 117:13	184:20,20
224:3,18,22	344:23 345:18	146:8 148:21	146:19 168:22	tend 344:7
225:10 226:13	346:1,18	165:5 173:11	235:17 274:13	term 130:19
226:25,25	355:14,21	174:17 186:23	task 330:19	131:3,4 146:25
232:19 233:2	356:10 361:5	201:7 221:8	331:3,8,11,12	183:4 194:4
236:10,12,19	361:15 370:15	265:1,3 268:9	333:25 347:25	216:15 303:2
237:3,14	talc's 86:21	276:3 294:5	tasks 330:17	termed 34:25
238:10 239:18	talcum 1:3 4:22	305:13 314:17	teaching 291:2	terms 27:24
240:10 241:16	29:20 198:2	327:21,25	teasing 293:23	74:10 75:23
241:21 242:1,5	200:3 251:4	335:3 355:25	technically	101:19 147:14
242:14,21	255:24 256:20	369:16	342:6,9	150:10 151:10
249:17 250:10	258:4,19 260:2	talking 15:14	Tecum 4:12	157:8 159:13
253:2 256:15	261:8 262:22	16:4 27:23	Ted 2:3 6:18	171:21 187:15
257:10,21	263:20 268:23	63:8,13 84:25	Ted.Meadows...	323:14
258:24,25	290:19 322:15	86:8 95:4	2:4	test 40:1 127:8

Confidential - Pursuant to Protective Order

Page 421

160:8 181:22	45:13 52:24	96:10,13,16	304:14 305:5,8	281:25 282:17
tested 132:19	53:18 57:9,14	97:9 99:6	311:12 318:6,6	282:18 283:11
139:24 248:1	57:15,22 61:12	100:21 101:3,5	318:16,24	284:14 294:22
252:11 257:10	62:5 63:19	101:9,23,23	319:7 320:4	295:5 303:4
testified 265:9	80:25 83:14	103:1 104:9	323:3,25 325:4	304:7,11,21
297:14	85:11 88:23	106:15 119:21	325:11 328:7	thresholds
testify 365:23	91:4 92:25	123:24 125:14	332:10 333:20	283:5
372:5	93:5 98:15,19	126:3,9,17	335:5,20 349:4	throw 143:13
testifying	101:13,20	136:4 139:20	349:10,18	tie 49:8
255:19 346:24	103:7 125:8	141:17 145:1	351:15,24	tied 334:16
347:2	133:12 140:9	146:8,23	355:15,23	tight 297:4
testimony 30:5	140:11 146:13	151:11 153:1	357:24 358:2	tightly 231:6
32:22 86:1	150:19 151:25	160:25 162:6	362:19 365:16	time 6:7 10:4,22
108:20,23	153:6 159:15	162:17 163:6	366:6,7 370:1	11:12,15,20,25
109:5,7 136:18	160:16,17	164:23 165:5	thinking 37:5	12:1 17:7
163:3 186:12	161:16 163:19	166:15,16,18	120:6 219:22	20:13,20 21:3
209:21 210:2	163:22,24	167:9,10 169:2	316:23 346:22	21:9 24:6
213:16 252:6	169:16 179:1	174:16 176:25	third 126:18	29:23 31:9
255:16 261:23	181:5,5 184:6	177:5 181:3,4	212:18	32:20,23 34:6
262:13,20	194:23,24	182:5,15	third-party	56:16 57:6,20
342:16,18	196:16 197:22	183:13 185:2	51:18	59:16 66:17
349:13,19	204:2 209:12	186:14,18	thirty 373:15	84:2 109:21,21
350:5 372:8	209:18 216:13	188:15,18	THOMAS 2:12	110:11 131:14
testing 142:20	225:14 233:13	189:5,7 190:7	3:7	136:16,24
170:5 182:13	234:3 235:18	190:20 191:24	thoroughly	139:1 163:11
182:21 186:5	247:8 269:22	192:2 200:17	94:16	164:21 165:10
187:23	289:4 293:19	202:14 203:8,9	thought 21:1	165:15,17,24
tests 144:7	305:23 312:23	203:19 204:22	38:21 58:9	170:8,24,25
181:18	315:18 323:16	223:9,13 224:7	77:25 92:2	176:7 177:8
Texas 1:19 3:4	323:18 324:13	224:24 227:16	100:23 108:19	179:5 215:23
372:21	328:18 330:14	233:9 234:13	108:20 215:10	226:14 228:12
textbook 292:11	331:15 335:19	237:8 238:22	233:10 330:4	230:25 231:5
294:6	343:15 349:10	242:1,25 243:8	347:2	265:17 286:7
textbooks	think 18:6 28:6	244:12,20	thousand 158:6	294:18 298:18
290:11	30:16 31:10	245:11 246:3	200:10	299:3,16
thank 7:16	32:21 33:9,13	247:15 248:11	thousands 346:6	301:21 302:9
111:21 287:13	34:15 38:20	249:20 256:24	three 12:7 13:5	302:15 303:23
318:25 370:16	41:15 48:23	257:1,8 260:6	13:6,15,21	306:13 331:2
370:17,20	49:16 50:11	261:11 275:3	19:8,11 27:25	345:23 346:1,4
theory 181:19	52:6 58:11,13	282:22,23	254:1 264:2	348:6,12 349:9
thing 10:1 16:8	58:16 61:22	283:11 284:13	268:1,5,8,15	356:6 358:17
63:9 326:6	66:23 68:18	287:1 288:15	278:21 279:23	361:11,14,17
333:9 355:4	72:23 76:6	294:5 297:7,25	280:14 290:23	364:10 365:11
things 18:3,5	80:15 82:23	298:10,23,25	301:17 310:3	367:23 368:5
22:1,7 29:6	83:19 84:15,17	299:16 301:23	threshold 39:17	370:24 372:9
30:5 36:16	90:13 91:15	302:11 303:6	39:24 200:2,7	timeline 15:14
43:13,16 45:13	93:22 95:14	303:12 304:12	237:10,13	138:22

times 62:24	368:18	242:1 254:6,10	101:15 103:12	165:6 186:23
82:10 114:4	today's 6:6 13:1	266:13,14,18	103:12 183:16	252:5 335:1,8
172:5,5,5	15:5 22:18	283:14 294:25	184:4 265:5,12	349:19
184:20,21	told 58:11	295:6	295:23,25	trials 20:21
199:2 201:20	103:24 171:22	toxicokinetics	297:1,18	335:3 349:13
216:2 253:22	185:12 209:6	65:6 67:12	302:10	tried 91:15
302:7 310:17	210:15 219:3,8	toxicological	tracts 101:11	92:12 141:3
311:17 316:4	245:5 257:12	114:10 167:3	trail 55:16	155:19 160:21
319:7 339:22	257:13 265:21	234:22 290:7	trained 86:7	174:15 185:2
341:13,19	307:17 315:17	304:10	115:12 352:10	191:5,5 192:22
362:14	Tom 7:3 319:5	toxicologist 72:5	352:15 359:14	201:22 307:5
timing 28:24	tool 75:24 77:13	84:18,25	training 39:6	triggered
343:6	356:5,9	126:10 143:16	77:23 84:23	146:20 266:10
Tinsley 3:12 7:5	tools 81:7	145:17 150:19	99:7 105:12	triggering 228:2
7:5	212:20 356:17	152:3 166:23	115:12 264:5	trimellitic
Tisi 2:13 6:24,24	top 52:3 184:1	167:16 168:3	356:5,7 357:9	135:22,25
19:3,4	218:10	170:1 181:24	transcript 372:8	trouble 333:23
tissue 125:5	topic 54:24	195:15 199:20	373:16,17	true 59:11 67:17
126:1 128:1	58:13,14 64:23	224:6 234:21	transcription	73:11 74:22
140:13 179:17	97:2 124:18	255:19 264:5	374:5	75:4 79:10
227:13,14	289:16	305:10 307:5	transcripts	84:3,11 105:25
228:5 229:1	topics 29:5	307:15 334:3	345:7,10	106:1,3 107:20
231:14 232:20	30:18 33:2,5	357:3	transition	118:20 127:10
242:22 264:15	33:22 53:5	toxicologists	124:17	136:11 157:9
264:16,24	58:15	72:25 85:4	transparency	164:7 171:24
274:1,8,8	Totally 326:8,19	115:4 281:6	213:12,15	174:5,12
276:19 283:14	touch 287:22	toxicology 29:20	214:4 219:20	177:23 195:10
289:8 293:4	toxic 29:24	76:9 77:10	244:15 350:17	207:7 213:7
tissues 273:24	125:4 145:20	81:20,23	transparent	227:4 230:10
title 69:3 290:25	146:18 151:19	125:25 182:21	212:21 214:9	232:22 233:15
tlocke@seyfar...	153:3 195:23	199:24 209:16	362:14	241:1 251:18
3:8	195:25 223:21	255:13 275:20	tremolite 135:10	282:13 284:23
today 8:8 12:5	242:4 243:13	278:5 291:1,3	145:19,21,21	293:9 294:15
23:21 34:10,23	273:23 306:8	294:1,5 295:2	147:16,20,21	294:25 295:16
51:16,20 60:21	306:11	295:10 304:25	147:22 148:10	296:1,12
88:21 109:10	toxicities 34:6	323:19 334:8	148:11,12,13	297:20 308:8
109:11,20	toxicity 39:13	335:2,4,12,25	148:25 149:20	316:25 317:5
110:23 119:12	86:21 126:2,22	346:11	149:22 150:6,8	320:10 332:11
120:23 145:16	127:17,20	trace 309:14,20	151:3,21	336:18 340:18
149:2 162:22	128:1 139:14	310:4,15,17,21	162:15 253:25	342:7 343:9,16
176:2 188:9	140:13 146:5	310:23 311:4	309:23	344:4 347:19
200:8 202:6	149:1,10,13	track 56:5,11	tremolite-cont...	359:15 361:20
209:21 210:2	150:4,24	80:5,24	149:23	361:21 363:12
250:11 259:22	151:17 152:14	tract 68:7 69:10	trial 20:25 21:19	363:25 367:6
276:25 280:23	169:20 224:15	69:15 70:6,11	21:21 22:7,11	truly 222:21
297:14 315:11	235:17 240:11	71:18 72:1	22:13 32:22	truth 7:22,22,23
354:24 368:15	241:16,21	73:16 95:20	109:23 138:20	372:6,6,6

try 61:2 77:24 93:20,21 98:23 102:15 129:9 141:17 145:11 152:9 162:4 163:8 198:10 228:22 229:14 319:11 339:6	172:4 204:1 233:4,16,16 279:25 280:1 281:7 283:8 289:4 290:21 292:16 313:18 318:7 323:17 323:18,22 324:13 329:8 329:14 330:14 330:16,17 349:4 363:4	254:9 267:18 269:18,23 270:6,8 271:15 271:16,25 273:12 311:23 typical 178:10 182:20 205:21 214:7 294:12 typically 36:25 42:12 52:14 63:11,17 80:12 80:12 107:5 114:14 122:22 199:21 205:19 253:20,21 261:19 307:15	151:16 152:4,7 152:13,22 155:13 167:17 169:2,8 170:4 175:1,19 195:16 204:14 213:9 219:22 229:14 231:3 233:3 234:7 247:6 262:15 281:12 283:20 291:20 297:13 304:9 325:5 328:22 330:13 332:18 333:20 338:7 357:5 360:5	unfortunately 59:16 74:2 166:21 170:11 185:24 225:14 237:7 239:4 297:20 Union 3:15 7:6 unique 103:9 United 1:1 6:11 322:19 universities 290:12 unsafe 347:5 up-to-date 10:15 update 62:8 updated 61:21 111:19 updating 61:14 62:5 upper 68:7 69:15 73:15 upright 101:12 101:13 upwards 95:20 usage 283:22 use 4:19 21:21 26:8 27:23 37:11 38:7 44:11 48:2 49:23 58:14 75:22 76:13 80:3,17 81:8,9 88:16 90:18 105:12 110:13 110:18 113:22 114:16,21,23 115:12 117:14 119:5 127:2 153:20 160:4 171:3 173:20 175:5,22,24 178:3,12 179:11 183:4,4 185:17 187:1,4 187:17 193:4 193:18 194:5
trying 28:19 53:2 57:11 73:2 78:5 106:15 117:14 119:16 128:5 130:15 133:6 151:14,16 153:14 155:22 156:14 169:11 195:15 219:18 238:5 243:19 259:14 260:19 269:13 273:20 289:1,1 304:6 306:3 316:5 347:23	two-thirds 236:7 type 55:22 81:3 84:19 116:25 133:16 135:2 138:3 140:13 140:20 145:8 147:22 159:4 162:11 172:20 215:18,25 232:20 233:20 254:20 269:18 270:12,13 271:15 272:2 286:11 326:20 327:15 348:18 type's 233:2 types 35:17 43:13 51:6 70:20 77:4 106:18 114:8 137:5,7 139:13 139:22 140:16 142:13 143:17 146:5,19 149:11 152:17 152:24 156:4 156:16 161:16 169:25 174:18 179:5 195:25 216:4 218:15 219:9 226:25 229:5 233:4,14 233:17 234:8 234:10,14,16	typical 178:10 182:20 205:21 214:7 294:12 typically 36:25 42:12 52:14 63:11,17 80:12 80:12 107:5 114:14 122:22 199:21 205:19 253:20,21 261:19 307:15 <hr/> U Uh-huh 122:20 286:1 304:8 Uhl 19:16 ultimate 127:17 237:12 ultimately 132:3 133:20 140:25 underlying 34:5 37:13 191:11 191:21 274:7 277:17 278:1 293:4 underpinnings 314:22 underpins 294:2 understand 23:25 28:6,19 32:22 33:1,3 48:24 57:11,17 67:1 82:19 83:20,20 88:20 93:25 94:2 102:4,23 104:21 113:15 114:3 117:15 128:5 133:15 134:11 142:12 148:17 150:20 151:12,15,15	understanding 8:8,12 10:6,19 19:10 21:8 22:17 29:17,18 34:24 35:2 40:4 44:13 47:22 55:19 98:12 101:5 108:25 109:16 116:15 123:15 125:23 130:3 131:2,4 132:14 133:18 136:20 150:2 154:1 169:5 194:3 202:7 213:1,20 249:8 308:21 understands 45:15 understood 63:2 182:10 227:19 242:10 329:6 349:9 undertook 330:18,18 underwear 296:22 297:17 298:4 299:6 unethical 185:25	unfortunately 59:16 74:2 166:21 170:11 185:24 225:14 237:7 239:4 297:20 Union 3:15 7:6 unique 103:9 United 1:1 6:11 322:19 universities 290:12 unsafe 347:5 up-to-date 10:15 update 62:8 updated 61:21 111:19 updating 61:14 62:5 upper 68:7 69:15 73:15 upright 101:12 101:13 upwards 95:20 usage 283:22 use 4:19 21:21 26:8 27:23 37:11 38:7 44:11 48:2 49:23 58:14 75:22 76:13 80:3,17 81:8,9 88:16 90:18 105:12 110:13 110:18 113:22 114:16,21,23 115:12 117:14 119:5 127:2 153:20 160:4 171:3 173:20 175:5,22,24 178:3,12 179:11 183:4,4 185:17 187:1,4 187:17 193:4 193:18 194:5

195:11,18	variety 21:6	364:15,18	183:22 188:16	364:9
196:14 198:12	58:23 70:20	368:24 369:2	195:12 201:5	water 117:16
198:23,25,25	248:7 253:21	370:24	204:4 212:4	way 34:20 35:20
199:17,21,21	274:16 293:19	videotaped 1:12	229:13,23	36:7 37:5,25
200:2 203:3	358:1 370:9	4:11 9:10	232:7 235:2,3	38:10,21 40:21
204:4 205:22	various 55:5	view 33:5 38:13	241:7 242:9	49:13 51:13
209:9,19 216:5	208:21 218:23	49:6 84:18,20	247:12 249:18	55:14 56:10
225:1 239:10	320:15 369:19	96:3 97:20	281:11 283:4	58:2 70:8
258:4,7 260:2	vary 232:19	127:14 165:7	287:22 305:17	73:19 78:22
263:20 282:25	vast 160:13	181:10 189:1	316:8,9 317:16	79:12 86:7
283:1,2,3	venturing 24:8	197:9 236:16	330:8,10,13	89:9 94:18
284:15 289:12	verbatim 372:8	254:8 258:2	333:19 347:7	98:22 101:1,16
296:15 301:25	verify 347:8	269:16 349:21	358:13 362:22	105:15 110:20
306:5,23 313:8	Vermont 136:22	vitro 115:5	364:8 366:20	115:6 130:12
324:13 327:17	Version 4:24	117:9 118:10	wanted 19:10	131:12 137:25
328:25 329:1	versus 38:11,11	142:5 205:24	56:18,20 57:17	138:24 140:8
334:25 347:18	67:4 72:18	207:5,20	61:6 105:18	142:10 144:14
356:6	76:14 79:16	208:16 217:1	133:14 159:13	144:21,22
uses 78:16	83:1 85:1	219:7 224:1	201:11 280:11	146:4,23 151:7
184:19 194:8	101:12,13,16	228:13,17	319:14 323:10	156:10 158:1
196:17 283:8	101:25 118:6	229:9,15,22,25	329:21	159:21 161:25
283:10 298:4	120:10 125:7	230:4 240:8,8	warm 301:8	171:3 172:19
302:8 339:19	126:6 140:18	vitro/only 217:5	warn 327:3,4	173:7 176:21
usually 18:7,10	146:9 150:15	vivo 229:10	328:8 329:15	185:1 191:4
63:16 64:6	151:6 163:9,10	230:2,2,7	332:16	192:9,12
93:20 261:22	165:1,2 170:15		warned 165:18	194:22 195:23
310:21	175:21 178:10	W	330:25 332:17	196:11 209:3
uterus 180:9	179:14,22	wait 242:8	warning 47:4	209:15 210:15
	181:2 205:7	waiting 301:2	48:14,14 52:13	230:16 231:22
V	219:7,7 224:22	walk 13:16	52:17 153:11	233:22 236:7
V 2:13 3:19	227:6 231:9	wander 137:18	166:12 179:2,3	240:15 241:3,5
VA 2:10	233:12,24,25	want 8:16 12:16	285:15,17	245:15 246:19
vagina 103:15	238:25 240:7,8	12:20 13:9	326:14 328:4	256:5 265:3
180:8 296:11	243:12 247:1	20:10,11 24:7	334:15,19	275:4 283:5
vaginal 296:23	260:11 264:17	27:6 30:14	warnings 51:7	291:21,22
Valley 164:9	266:19 270:21	41:12 60:5	141:25 165:18	293:6 297:22
valuable 88:8	281:8 283:9	72:16 74:12	285:15,20	298:5,24 300:6
value 87:4,10	305:14 314:21	78:24 94:19	330:22 331:17	302:9 314:24
106:10 160:22	324:20 326:14	100:10 102:18	Washington 3:9	319:21,24
values 78:12	327:18 357:17	106:5 109:24	wasn't 15:10	320:1 325:10
79:6 89:3	Vetner 16:6	110:8 119:1	21:14 59:20	332:1,11
105:19 219:4	videographer	120:6 121:7	62:3 119:14	353:17 354:9
variable 199:18	6:1,4 7:16 25:9	123:24 129:15	123:19 171:22	356:17 362:5
varied 251:7	25:12 94:22,25	135:18 148:15	257:13 262:11	366:23
267:15	99:21,24 188:3	149:4,5 150:3	334:2 345:21	ways 58:24
varies 128:22	188:6 200:21	153:11 162:15	349:22 353:5	78:10 80:24
134:22	200:24 287:3,6	169:13 177:4,8	waste 177:8	219:19 256:18

294:20	87:6,14 88:5	90:5 98:23	160:11 162:2	women 37:4
we'll 11:6 17:12	88:17 89:5,24	99:3 116:9	163:6 164:12	41:4 70:11
39:15 70:2	90:10,18 93:6	well-controlled	165:12 166:15	185:11 186:1
166:3 252:24	95:25 96:6	172:18	171:6 173:23	198:23 199:13
359:3	97:3,6,21 98:4	well-recognized	174:10 176:6	202:19 203:22
we're 13:8 24:7	98:7,9,21 99:2	290:11	179:13 180:18	237:13 265:5
63:8 64:18	101:8 102:4,23	went 12:12,13	184:25 186:13	296:15,20
78:25 84:22	103:5,20,22	15:16 61:1,8	187:19 190:15	women's 312:3
94:22 194:16	104:3,5,12	61:12 77:4	192:19 195:7	Woodruff 16:5
194:17 226:5	105:11,15	123:9 246:15	196:9 198:9	102:21,22
323:11 361:24	107:2 112:17	weren't 21:11	214:19 221:5	105:3 296:2
368:22,22	112:21 113:16	21:22 22:1,8	222:11 233:7	word 57:2 59:22
we've 22:21	114:6,12,12	60:2 83:3	234:13 238:15	60:22 64:11,13
138:20,21	115:25 117:8	163:19 239:6	239:23 241:20	110:18 127:3
174:17 206:15	120:4,10,11,19	318:13	252:18 255:11	157:22 172:1
369:16	121:2 133:23	wide 358:1	259:14 260:6	187:4 194:5
weakened	134:11 135:7	widespread	261:17 262:25	195:13 216:5
110:11	140:23 141:4,5	258:17	270:15 278:17	237:9 300:20
weaknesses	143:18 154:16	William 2:22	279:15 282:4	354:18
102:16	155:6,16	7:12	283:25 284:19	words 22:3
weather 301:9	172:21 173:2	Wilma 352:20	287:13 291:10	34:15 45:14
web 288:14	198:12 205:15	wiped 299:8	292:21 296:5	53:20 56:22
website 17:5	209:10 210:1,9	witness 7:19	296:19 298:7	58:20 126:3
109:9 212:13	210:21,23,25	28:11,22 32:4	298:23 300:4	136:13 137:18
284:11,22	211:3,4,10,11	33:9 38:20	303:9,15	146:16 149:11
288:11,15	213:2 214:15	39:23 40:18	306:10 307:14	156:8 169:15
341:8 345:11	215:20,24	45:3 48:23	307:24 308:7	183:21 187:2
345:16	217:19,24	49:11 50:6	308:17 309:17	191:7 194:13
websites 26:16	218:18,24	51:4,24 56:8	310:9 312:10	195:18 203:2
123:19	219:1,12 229:9	58:7 72:3	315:5 316:23	204:4 216:1
WEDNESDAY	229:12 230:6	73:18 86:3	321:21 322:21	239:6 242:19
1:8	230:10,18	87:9 89:20	325:4,22 327:8	257:4 294:19
week 9:3,3	231:18,19	90:13 91:25	329:12 330:3	305:11
300:1,24	232:1 236:8	93:18 96:10	332:10 334:21	work 10:16
weekly 302:3	240:4 244:1,14	99:6 105:24	340:22 342:25	18:22 19:21
weigh 38:8	244:19,19,19	106:14 107:16	350:23 351:21	20:7 22:24
106:19 199:8	244:23,25	111:18,22	353:23 356:13	23:7 24:8,14
217:24 247:12	245:14,18,23	113:20 118:17	356:25 369:25	26:2 29:9 44:7
weighed 135:12	246:13,19	121:4 127:1	370:20 373:1	45:24 54:5
184:6 205:5,10	248:6 252:12	131:18 132:6	WOE 212:23	56:2 69:5
weight 5:1 41:21	252:19,24	134:1,16 136:4	213:2	74:14 82:1,7
42:4,24 73:21	285:21 314:1	137:12,16,22	woman 296:24	121:22 162:8
75:24 77:13,20	314:11 315:1	139:18 141:3	296:25 297:5	213:23 216:19
78:3,10 80:7	315:18	143:9 144:10	298:4,18 302:7	217:3 218:19
82:21 83:7,21	weighted 77:17	145:1,24	302:8 352:23	244:11 245:25
84:5,12 85:5,7	231:24	154:22 155:19	354:15	247:9,13 248:2
85:22 86:10,23	weighting 41:22	157:8 159:8	woman's 200:16	255:18 286:24

351:6,9,11	196:23 202:3	129:11 158:5	363:5	213 2:24
362:18 365:5	227:7 261:14	174:7	1997 68:4 69:3	215 2:19
365:21	269:12 298:16	10:41 94:23,24	70:23	218 2:5
worked 20:20	318:11 368:21	10:56 95:1		22 46:24 111:19
43:17 50:8	year 20:3 54:14	100 3:13 223:13	2	22311 2:10
52:9 248:9,14	54:17,25 62:11	338:16 366:21	2 4:3,13 13:17	23 336:20
248:19 262:6,8	102:25 300:25	11 212:16	14:7,11 28:1,4	25 128:25
262:13 346:23	301:4,7,10	11:00 99:22,23	29:2,2 33:7	26 4:16
346:25	302:4 303:1,7	11:01 99:25	57:24 64:19	269-2343 2:6
working 10:23	304:13	111 4:23	290:19	278-4449 2:19
11:19 45:22	years 28:25 31:5	112 3:3	2:57 287:4,5	28 65:15
82:11 116:19	82:10 108:11	118 315:21	20 174:8 339:22	287 4:6
334:7 344:18	136:21 199:21	316:12	374:16	29 4:15 14:16
344:22	199:23 302:21	12 112:10 236:3	200 129:7	20:3 183:12
workload	305:14 307:11	12/20/18 372:23	130:13	267:3
347:24	307:15 320:13	12:23 188:4,5	2000 290:15	2900 2:18
works 344:19	321:7	12:24 188:7	20004 3:9	2B 197:6,8
workshop 361:4	yellow 80:14,17	12:36 200:22,23	2005 365:3,5,12	198:6
worried 291:11	218:10	13 4:13,14,16	365:24	2nd 1:14
wouldn't 73:7,9	Yep 211:23	76:18 77:19	2006 324:24	
73:18 81:25	yesterday 10:9	78:23 90:20	2008 363:3,6,9	3
92:6 99:3	10:14 11:21	92:4	363:10	3 4:14 13:17
122:16 235:20	12:2,9 13:10	13921 372:19	2009 361:19	14:14,18 20:4
257:3 282:11	17:19 19:5	14 111:17	362:23 363:14	23:9 28:1,4
319:20 337:16	35:9 42:18	16 4:17,18 14:22	364:24 365:10	29:3 33:7
355:5	186:24 257:14	22:20	2010 65:10,22	57:24 266:22
write 80:18 81:1	263:24 297:14	16-2738 1:4	2012 341:16	3:13 287:7
322:21 323:6	yesterday's	17 4:21	2013 65:10,23	30 147:8,12
350:11,18	11:15 19:24	1715 372:22	66:6,12 67:14	172:10 173:1,5
write-up 356:15	York 135:23,25	18 112:10	95:5 96:21	173:14,19
writing 25:21	140:24	1800 3:3	120:3,3 210:18	299:6 373:15
32:24 74:17		1835 2:18	2015 19:25	31 124:12
247:17	Z	1894 136:14	2016 4:13 14:8	336:24
written 90:15		19 1:8 6:6 147:9	19:15 21:4,12	314 3:14
91:9,12 104:21	0	317:20	65:25 118:14	316 2:14
121:15 350:24	01 40:16,19	19103 2:18	118:25 120:1	319 4:7
361:24 365:3	084-004229	1948 15:21	2018 1:8 4:15,17	32 249:24
wrong 16:15	372:21	1950s 316:14,21	6:7 14:16,22	250:13
198:14 208:7	09 365:4	317:20 318:1	20:3,9,13 21:5	32502 2:14
wrote 21:15	1	318:21	22:21 23:3	333 2:23
317:3 331:14	1 4:11 8:13,18	1980s 317:10	111:17,19	334 2:6
338:4,5	9:8 29:2 40:7	1981 68:4	267:3	35 166:3 321:7
X	158:5	1989 317:9	202 3:9	336:20
	1:35 200:25	1991 249:7	21 46:21 47:2,25	36 267:23
Y	10 53:7 54:8	1992 65:10,22	64:16,19	36104 2:6
yeah 40:9	64:20 124:25	363:5	210 3:4	37 100:3 134:21
		1994 361:4	211 5:1	38 15:13 242:9

Confidential - Pursuant to Protective Order

Page 427

39 16:1	58 242:9,12	9:12 1:15 6:7		
<hr/>	<hr/>	9:30 25:10,11		
4	6	9:32 25:13		
4 4:16 13:17	6 4:21 17:9,14	90 365:2,12		
14:20,25 15:7	86:14 202:15	366:5		
22:21 23:13	267:13	90071 2:23		
24:13 25:19	600 2:14 3:13	90s 31:7		
26:25 28:1,5	63 367:8	917.591.5672		
46:24 53:6	63102 3:14	1:22		
57:24 64:3	64 313:15	93 231:1		
65:14 66:11	65 188:18 190:7	931-5500 2:10		
75:3,12,18	650 2:9	9328 372:21		
76:5 90:8	67 188:21 190:8	95 367:8		
93:16 95:11	266:23 313:13	975 3:8		
113:12 155:14	68 289:17,24	99.9 121:5		
201:10 206:22	680-8370 2:24	999 1:14		
209:23 210:22	69 280:19			
4:23 364:16,17	<hr/>			
4:25 364:19	7			
4:30 368:25	7 4:23 53:8,9			
369:1	111:4,9,13			
4:45 369:3	112:6 124:2			
4:47 370:25	208:9 318:16			
371:3	70 145:19 167:1			
40 64:3	338:17			
400 129:7	703 2:10			
43 65:15 66:10	70s 165:1			
68:1,17 183:12	740.1 46:21 47:3			
435-7000 2:15	47:25			
44 103:2 313:17	75 125:1 128:25			
46 313:14	77 316:12			
463-2400 3:9	78205 3:4			
47 280:19	<hr/>			
289:17,24	8			
4900 2:9	8 4:5,11 5:1			
<hr/>	208:9 211:14			
5	211:18,21			
5 4:13,18 14:8	219:16 236:4			
16:3,16,23	80s 165:2			
19:14 86:13	850 2:15			
124:25 206:16	859 372:20			
206:21	877.370.3377			
50 347:11	1:22			
351:16	89 318:8 366:4			
554-5500 3:4	<hr/>			
56 95:12,16	9			
571-4965 3:14	9 208:9			

Exhibit V

WORLD HEALTH ORGANIZATION
INTERNATIONAL AGENCY FOR RESEARCH ON CANCER



IARC Monographs on the Evaluation of Carcinogenic Risks to Humans

VOLUME 93

Carbon Black, Titanium Dioxide, and Talc



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WORLD HEALTH ORGANIZATION
INTERNATIONAL AGENCY FOR RESEARCH ON CANCER



***IARC Monographs on the Evaluation of
Carcinogenic Risks to Humans***

VOLUME 93

**Carbon Black, Titanium Dioxide,
and Talc**

This publication represents the views and expert opinions
of an IARC Working Group on the
Evaluation of Carcinogenic Risks to Humans,
which met in Lyon,

7–14 February 2006

2010

IARC MONOGRAPHS

In 1969, the International Agency for Research on Cancer (IARC) initiated a programme on the evaluation of the carcinogenic risk of chemicals to humans involving the production of critically evaluated monographs on individual chemicals. The programme was subsequently expanded to include evaluations of carcinogenic risks associated with exposures to complex mixtures, lifestyle factors and biological and physical agents, as well as those in specific occupations. The objective of the programme is to elaborate and publish in the form of monographs critical reviews of data on carcinogenicity for agents to which humans are known to be exposed and on specific exposure situations; to evaluate these data in terms of human risk with the help of international working groups of experts in chemical carcinogenesis and related fields; and to indicate where additional research efforts are needed. The lists of IARC evaluations are regularly updated and are available on the Internet at <http://monographs.iarc.fr/>.

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doctoral theses and other material that are in their final form and publicly available may be reviewed.

Exposure data and other information on an agent under consideration are also reviewed. In the sections on chemical and physical properties, on analysis, on production and use and on occurrence, published and unpublished sources of information may be considered.

Inclusion of a study does not imply acceptance of the adequacy of the study design or of the analysis and interpretation of the results, and limitations are clearly outlined in square brackets at the end of each study description (see Part B). The reasons for not giving further consideration to an individual study also are indicated in the square brackets.

5. Meeting participants

Five categories of participant can be present at *Monograph* meetings.

(a) **The Working Group** is responsible for the critical reviews and evaluations that are developed during the meeting. The tasks of Working Group Members are: (i) to ascertain that all appropriate data have been collected; (ii) to select the data relevant for the evaluation on the basis of scientific merit; (iii) to prepare accurate summaries of the data to enable the reader to follow the reasoning of the Working Group; (iv) to evaluate the results of epidemiological and experimental studies on cancer; (v) to evaluate data relevant to the understanding of mechanisms of carcinogenesis; and (vi) to make an overall evaluation of the carcinogenicity of the exposure to humans. **Working Group Members generally have published significant research related to the carcinogenicity of the agents being reviewed, and IARC uses literature searches to identify most experts. Working Group Members are selected on the basis of (a) knowledge and experience and (b) absence of real or apparent conflicts of interests. Consideration is also given to demographic diversity and balance of scientific findings and views.**

(b) Invited Specialists are experts who also have critical knowledge and experience but have a real or apparent conflict of interests. These experts are invited when necessary to assist in the Working Group by contributing their unique knowledge and experience during subgroup and plenary discussions. They may also contribute text on non-influential issues in the section on exposure, such as a general description of data on production and use (see Part B, Section 1). Invited Specialists do not serve as meeting chair or subgroup chair, draft text that pertains to the description or interpretation of cancer data, or participate in the evaluations.

(c) Representatives of national and international health agencies often attend meetings because their agencies sponsor the programme or are interested in the subject of a meeting. Representatives do not serve as meeting chair or subgroup chair, draft any part of a *Monograph*, or participate in the evaluations.

(d) Observers with relevant scientific credentials may be admitted to a meeting by IARC in limited numbers. Attention will be given to achieving a balance of Observers

analyses. Irrespective of the source of data for the meta-analyses and pooled analyses, it is important that the same criteria for data quality be applied as those that would be applied to individual studies and to ensure also that sources of heterogeneity between studies be taken into account.

(d) Temporal effects

Detailed analyses of both relative and absolute risks in relation to temporal variables, such as age at first exposure, time since first exposure, duration of exposure, cumulative exposure, peak exposure (when appropriate) and time since cessation of exposure, are reviewed and summarized when available. Analyses of temporal relationships may be useful in making causal inferences. In addition, such analyses may suggest whether a carcinogen acts early or late in the process of carcinogenesis, although, at best, they allow only indirect inferences about mechanisms of carcinogenesis.

(e) Use of biomarkers in epidemiological studies

Biomarkers indicate molecular, cellular or other biological changes and are increasingly used in epidemiological studies for various purposes (IARC, 1991; Vainio *et al.*, 1992; Toniolo *et al.*, 1997; Vineis *et al.*, 1999; Buffler *et al.*, 2004). These may include evidence of exposure, of early effects, of cellular, tissue or organism responses, of individual susceptibility or host responses, and inference of a mechanism (see Part B, Section 4b). This is a rapidly evolving field that encompasses developments in genomics, epigenomics and other emerging technologies.

Molecular epidemiological data that identify associations between genetic polymorphisms and interindividual differences in susceptibility to the agent(s) being evaluated may contribute to the identification of carcinogenic hazards to humans. If the polymorphism has been demonstrated experimentally to modify the functional activity of the gene product in a manner that is consistent with increased susceptibility, these data may be useful in making causal inferences. Similarly, molecular epidemiological studies that measure cell functions, enzymes or metabolites that are thought to be the basis of susceptibility may provide evidence that reinforces biological plausibility. It should be noted, however, that when data on genetic susceptibility originate from multiple comparisons that arise from subgroup analyses, this can generate false-positive results and inconsistencies across studies, and such data therefore require careful evaluation. If the known phenotype of a genetic polymorphism can explain the carcinogenic mechanism of the agent being evaluated, data on this phenotype may be useful in making causal inferences.

(f) Criteria for causality

After the quality of individual epidemiological studies of cancer has been summarized and assessed, a judgement is made concerning the strength of evidence that the agent in question is carcinogenic to humans. In making its judgement, the Working Group

considers several criteria for causality (Hill, 1965). A strong association (e.g. a large relative risk) is more likely to indicate causality than a weak association, although it is recognized that estimates of effect of small magnitude do not imply lack of causality and may be important if the disease or exposure is common. Associations that are replicated in several studies of the same design or that use different epidemiological approaches or under different circumstances of exposure are more likely to represent a causal relationship than isolated observations from single studies. If there are inconsistent results among investigations, possible reasons are sought (such as differences in exposure), and results of studies that are judged to be of high quality are given more weight than those of studies that are judged to be methodologically less sound.

If the risk increases with the exposure, this is considered to be a strong indication of causality, although the absence of a graded response is not necessarily evidence against a causal relationship. The demonstration of a decline in risk after cessation of or reduction in exposure in individuals or in whole populations also supports a causal interpretation of the findings.

A number of scenarios may increase confidence in a causal relationship. On the one hand, an agent may be specific in causing tumours at one site or of one morphological type. On the other, carcinogenicity may be evident through the causation of multiple tumour types. Temporality, precision of estimates of effect, biological plausibility and coherence of the overall database are considered. Data on biomarkers may be employed in an assessment of the biological plausibility of epidemiological observations.

Although rarely available, results from randomized trials that show different rates of cancer among exposed and unexposed individuals provide particularly strong evidence for causality.

When several epidemiological studies show little or no indication of an association between an exposure and cancer, a judgement may be made that, in the aggregate, they show evidence of lack of carcinogenicity. Such a judgement requires firstly that the studies meet, to a sufficient degree, the standards of design and analysis described above. Specifically, the possibility that bias, confounding or misclassification of exposure or outcome could explain the observed results should be considered and excluded with reasonable certainty. In addition, all studies that are judged to be methodologically sound should (a) be consistent with an estimate of effect of unity for any observed level of exposure, (b) when considered together, provide a pooled estimate of relative risk that is at or near to unity, and (c) have a narrow confidence interval, due to sufficient population size. Moreover, no individual study nor the pooled results of all the studies should show any consistent tendency that the relative risk of cancer increases with increasing level of exposure. It is important to note that evidence of lack of carcinogenicity obtained from several epidemiological studies can apply only to the type(s) of cancer studied, to the dose levels reported, and to the intervals between first exposure and disease onset observed in these studies. Experience with human cancer indicates that the period from first exposure to the development of clinical cancer is sometimes longer than 20 years; latent periods substantially shorter than 30 years cannot provide evidence for lack of carcinogenicity.

(d) Mechanistic and other relevant data

Data relevant to the toxicokinetics (absorption, distribution, metabolism, elimination) and the possible mechanism(s) of carcinogenesis (e.g. genetic toxicity, epigenetic effects) are summarized. In addition, information on susceptible individuals, populations and life-stages is summarized. This section also reports on other toxic effects, including reproductive and developmental effects, as well as additional relevant data that are considered to be important.

6. Evaluation and rationale

Evaluations of the strength of the evidence for carcinogenicity arising from human and experimental animal data are made, using standard terms. The strength of the mechanistic evidence is also characterized.

█ recognized that the criteria for these evaluations, described below, cannot encompass all of the factors that may be relevant to an evaluation of carcinogenicity. In considering all of the relevant scientific data, the Working Group may assign the agent to a higher or lower category than a strict interpretation of these criteria would indicate.

These categories refer only to the strength of the evidence that an exposure is carcinogenic and not to the extent of its carcinogenic activity (potency). A classification may change as new information becomes available.

An evaluation of the degree of evidence is limited to the materials tested, as defined physically, chemically or biologically. When the agents evaluated are considered by the Working Group to be sufficiently closely related, they may be grouped together for the purpose of a single evaluation of the degree of evidence.

(a) Carcinogenicity in humans

The evidence relevant to carcinogenicity from studies in humans is classified into one of the following categories:

Sufficient evidence of carcinogenicity: The Working Group considers that a causal relationship has been established between exposure to the agent and human cancer. That is, a positive relationship has been observed between the exposure and cancer in studies in which chance, bias and confounding could be ruled out with reasonable confidence. A statement that there is *sufficient evidence* is followed by a separate sentence that identifies the target organ(s) or tissue(s) where an increased risk of cancer was observed in humans. Identification of a specific target organ or tissue does not preclude the possibility that the agent may cause cancer at other sites.

Limited evidence of carcinogenicity: A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.

Inadequate evidence of carcinogenicity: The available studies are of insufficient quality, consistency or statistical power to permit a conclusion regarding the presence or absence of a causal association between exposure and cancer, or no data on cancer in humans are available.

Evidence suggesting lack of carcinogenicity: There are several adequate studies covering the full range of levels of exposure that humans are known to encounter, which are mutually consistent in not showing a positive association between exposure to the agent and any studied cancer at any observed level of exposure. The results from these studies alone or combined should have narrow confidence intervals with an upper limit close to the null value (e.g. a relative risk of 1.0). Bias and confounding should be ruled out with reasonable confidence, and the studies should have an adequate length of follow-up. A conclusion of *evidence suggesting lack of carcinogenicity* is inevitably limited to the cancer sites, conditions and levels of exposure, and length of observation covered by the available studies. In addition, the possibility of a very small risk at the levels of exposure studied can never be excluded.

In some instances, the above categories may be used to classify the degree of evidence related to carcinogenicity in specific organs or tissues.

When the available epidemiological studies pertain to a mixture, process, occupation or industry, the Working Group seeks to identify the specific agent considered most likely to be responsible for any excess risk. The evaluation is focused as narrowly as the available data on exposure and other aspects permit.

(b) Carcinogenicity in experimental animals

Carcinogenicity in experimental animals can be evaluated using conventional bioassays, bioassays that employ genetically modified animals, and other in-vivo bioassays that focus on one or more of the critical stages of carcinogenesis. In the absence of data from conventional long-term bioassays or from assays with neoplasia as the end-point, consistently positive results in several models that address several stages in the multistage process of carcinogenesis should be considered in evaluating the degree of evidence of carcinogenicity in experimental animals.

The evidence relevant to carcinogenicity in experimental animals is classified into one of the following categories:

Sufficient evidence of carcinogenicity: The Working Group considers that a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumours in both sexes of a single

PREAMBLE

33

species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide *sufficient evidence*.

A single study in one species and sex might be considered to provide *sufficient evidence of carcinogenicity* when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumour or age at onset, or when there are strong findings of tumours at multiple sites.

Limited evidence of carcinogenicity: The data suggest a carcinogenic effect but are limited for making a definitive evaluation because, e.g. (a) the evidence of carcinogenicity is restricted to a single experiment; (b) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies; (c) the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or (d) the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.

Inadequate evidence of carcinogenicity: The studies cannot be interpreted as showing either the presence or absence of a carcinogenic effect because of major qualitative or quantitative limitations, or no data on cancer in experimental animals are available.

Evidence suggesting lack of carcinogenicity: Adequate studies involving at least two species are available which show that, within the limits of the tests used, the agent is not carcinogenic. A conclusion of *evidence suggesting lack of carcinogenicity* is inevitably limited to the species, tumour sites, age at exposure, and conditions and levels of exposure studied.

(c) *Mechanistic and other relevant data*

Mechanistic and other evidence judged to be relevant to an evaluation of carcinogenicity and of sufficient importance to affect the overall evaluation is highlighted. This may include data on preneoplastic lesions, tumour pathology, genetic and related effects, structure–activity relationships, metabolism and toxicokinetics, physicochemical parameters and analogous biological agents.

The strength of the evidence that any carcinogenic effect observed is due to a particular mechanism is evaluated, using terms such as ‘weak’, ‘moderate’ or ‘strong’. The Working Group then assesses whether that particular mechanism is likely to be operative in humans. The strongest indications that a particular mechanism operates in humans derive from data on humans or biological specimens obtained from exposed humans. The data may be considered to be especially relevant if they show that the agent in question has caused changes in exposed humans that are on the causal pathway to carcinogenesis. Such data may, however, never become available, because it is at least conceivable that certain compounds may be kept from human use solely on the basis of evidence of their toxicity and/or carcinogenicity in experimental systems.

The conclusion that a mechanism operates in experimental animals is strengthened by findings of consistent results in different experimental systems, by the demonstration of

biological plausibility and by coherence of the overall database. Strong support can be obtained from studies that challenge the hypothesized mechanism experimentally, by demonstrating that the suppression of key mechanistic processes leads to the suppression of tumour development. The Working Group considers whether multiple mechanisms might contribute to tumour development, whether different mechanisms might operate in different dose ranges, whether separate mechanisms might operate in humans and experimental animals and whether a unique mechanism might operate in a susceptible group. The possible contribution of alternative mechanisms must be considered before concluding that tumours observed in experimental animals are not relevant to humans. An uneven level of experimental support for different mechanisms may reflect that disproportionate resources have been focused on investigating a favoured mechanism.

For complex exposures, including occupational and industrial exposures, the chemical composition and the potential contribution of carcinogens known to be present are considered by the Working Group in its overall evaluation of human carcinogenicity. The Working Group also determines the extent to which the materials tested in experimental systems are related to those to which humans are exposed.

(d) Overall evaluation

Finally, the body of evidence is considered as a whole, in order to reach an overall evaluation of the carcinogenicity of the agent to humans.

An evaluation may be made for a group of agents that have been evaluated by the Working Group. In addition, when supporting data indicate that other related agents, for which there is no direct evidence of their capacity to induce cancer in humans or in animals, may also be carcinogenic, a statement describing the rationale for this conclusion is added to the evaluation narrative; an additional evaluation may be made for this broader group of agents if the strength of the evidence warrants it.

The agent is described according to the wording of one of the following categories, and the designated group is given. The categorization of an agent is a matter of scientific judgement that reflects the strength of the evidence derived from studies in humans and in experimental animals and from mechanistic and other relevant data.

Group 1: The agent is *carcinogenic to humans*.

This category is used when there is *sufficient evidence of carcinogenicity* in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity in humans is less than *sufficient* but there is *sufficient evidence of carcinogenicity* in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.

Group 2.

This category includes agents for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost *sufficient*, as well as those for which, at the other extreme, there are no human data but for which there is evidence of

PREAMBLE

35

carcinogenicity in experimental animals. Agents are assigned to either Group 2A (*probably carcinogenic to humans*) or Group 2B (*possibly carcinogenic to humans*) on the basis of epidemiological and experimental evidence of carcinogenicity and mechanistic and other relevant data. The terms *probably carcinogenic* and *possibly carcinogenic* have no quantitative significance and are used simply as descriptors of different levels of evidence of human carcinogenicity, with *probably carcinogenic* signifying a higher level of evidence than *possibly carcinogenic*.

Group 2A: The agent is *probably carcinogenic to humans*.

This category is used when there is *limited evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals. In some cases, an agent may be classified in this category when there is *inadequate evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals and strong evidence that the carcinogenesis is mediated by a mechanism that also operates in humans. Exceptionally, an agent may be classified in this category solely on the basis of *limited evidence of carcinogenicity* in humans. An agent may be assigned to this category if it clearly belongs, based on mechanistic considerations, to a class of agents for which one or more members have been classified in Group 1 or Group 2A.

Group 2B: The agent is *possibly carcinogenic to humans*.

This category is used for agents for which there is *limited evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals. It may also be used when there is *inadequate evidence of carcinogenicity* in humans but there is *sufficient evidence of carcinogenicity* in experimental animals. In some instances, an agent for which there is *inadequate evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data.

Group 3: The agent is *not classifiable as to its carcinogenicity to humans*.

This category is used most commonly for agents for which the evidence of carcinogenicity is *inadequate* in humans and *inadequate* or *limited* in experimental animals.

Exceptionally, agents for which the evidence of carcinogenicity is *inadequate* in humans but *sufficient* in experimental animals may be placed in this category when there is strong evidence that the mechanism of carcinogenicity in experimental animals does not operate in humans.

Agents that do not fall into any other group are also placed in this category.

5. Summary of Data Reported

5.1 Exposure data

The term 'talc' refers to both mineral talc and industrial mineral products that contain mineral talc in proportions that range from about 35% to almost 100% and are marketed under the name talc. Mineral talc occurs naturally in many regions of the world where metamorphosed mafic and ultramafic rocks or magnesium carbonates occur. Mineral talc is usually platy but may also occur as asbestiform fibres. (Asbestiform refers to a habit (pattern) of mineral growth and not to the presence of other minerals. Asbestiform talc must not be confused with talc that contains asbestos.) Together with platy talc, asbestiform talc is found in the Gouverneur District of New York State, USA, and occasionally elsewhere; it may be associated with other minerals as observed by transmission electron microscopy.

Talc products vary in their particle size, associated minerals and talc content depending on their source and application. Minerals commonly found in talc products include chlorite and carbonate. Less commonly, talc products contain tremolite, anthophyllite and serpentine.

Mineral talc is valued for its softness, platyness, inertness and ability to absorb organic matter. It is used in agricultural products, ceramics, paint and other coatings, paper, plastics, roofing, rubber, cosmetics and pharmaceuticals and for waste treatment. Cosmetic talc, which contains more than 90% mineral talc, is present in many cosmetic products and is used for many purposes, including baby powders and feminine hygiene products. The type of talc that is currently used for cosmetic purposes in the USA does not contain detectable levels of amphibole, including asbestos. It is not known whether this is true in other countries.

Workers are exposed to talc during its mining and milling. Reported geometric mean exposure levels to respirable dust are typically in the range of 1–5 mg/m³. Workers may also be exposed in user industries, primarily in the rubber, pulp and paper and ceramics industries. Due to the presence of other particulates, exposure levels may be difficult to measure accurately. Consumer exposure by inhalation could occur during the use of loose powders that contain talc.

Accurate estimates of prevalence are not available. However, in some series of controls from epidemiological studies of ovarian cancer, the prevalence of use for feminine hygiene of body powders, baby powders, talcum powders and deodorizing powders, most of which contain cosmetic talc in varying amounts, has been reported to be as high as 50% in some countries. Perineal use for such purposes seems to have been a common practice in Australia, Canada, the United Kingdom, the USA and other countries, including Pakistan. Use of cosmetic talc in the USA has declined steadily since the late 1970s.

5.2 Human carcinogenicity data

The carcinogenic effect of exposure to talc not contaminated by asbestos fibres has been investigated in five independent but relatively small cohort studies of talc miners and millers in Austria, France, Italy, Norway and the USA. The miners and to a lesser extent the millers in these cohorts were also exposed to quartz. In a case-control study nested in the combined cohorts of talc workers from Austria and France, there was no tendency of higher risks for lung cancer by increasing cumulative exposure of workers to talc dust. In four of five studies, it was explicitly stated that no case of mesothelioma was observed. In the two studies from Italy and Norway, which included an estimate of cumulative exposure of the cohort to talc dust, the risk for lung cancer in the highest category was found to be close to or below unity. In the subgroup of miners in the study in the USA, an excess risk for lung cancer was found, which may have been due to exposure in the workplace to radon daughters and quartz. In all the other groups of workers studied, there was no increased risk for lung cancer.

Female workers in the Norwegian pulp and paper industry had an increased risk for ovarian cancer, which, however, was attributed to exposure to asbestos. A community-based case-control study did not find an increased risk for ovarian cancer associated with occupational exposure to talc, but the prevalence of exposure was low.

Body powder containing talc has been used by women on the perineum (or genital area), on sanitary napkins and on diaphragms. In total, data from one prospective cohort study and 19 case control studies were reviewed in the evaluation of the association of cosmetic talc use and the risk for ovarian cancer. The information collected on perineal talc use varied substantially by study (e.g. ever use versus regular use, and whether information on the mode of application, frequency or duration of use was available).

The cohort study was conducted among nurses in the USA and included 307 cases of ovarian cancer that occurred over 900 000 person years of observation and a maximum of 14 years of follow-up. Information was collected on the frequency but not duration of regular use. Perineal use of talc was not associated with a risk for ovarian cancer.

The 20 case control studies were conducted in Australia, Canada, China, Greece, Israel, Norway, the United Kingdom and the USA (nested case control study), and included between 77 and 824 cases and 46 and 1367 controls. Five were hospital-based designs and the others were population-based studies. The Working Group designated a subset of these studies as being more informative based on the following characteristics: the study was population-based, was of a reasonable size, had acceptable participation rates and included information to allow control for potentially important confounders.

Eight population-based case control studies from Australia, Canada (Ontario) and the USA (two non-overlapping studies in Boston, MA, and one each in California, Delaware Valley, eastern Massachusetts and New Hampshire and Washington State) were thereby identified as being more informative. The selected studies included at least 188 cases and had participation rates that generally ranged from 60 to 75%. Among these eight studies, the prevalence of use of body powder among controls ranged from 16 to 52%; however,

information on exposure was not collected in a comparable manner across studies. In addition, the frequency and duration of use or total lifetime applications were investigated in several studies as well as consideration of prior tubal ligation or simple hysterectomy. Only sparse data were available on whether women had used body powder before or after the mid-1970s.

The relative risks for ovarian cancer among users of body powder (versus non-users) were homogenous across this relatively diverse set of eight studies, each of which indicated a 30–60% increase in risk. Among the other 11 case–control studies, most also reported relative risks of this magnitude or higher. The subset of studies that assessed use of talc on a diaphragm were relatively uninformative due to their lack of precision.

Results on exposure–response relationships were presented in the cohort study and in seven of the more informative case–control studies. In the cohort study, no exposure–response trend was apparent. Positive exposure–response trends were apparent in the two Boston-based studies that presented the most comprehensive analysis. In the Canadian and Californian studies, a non-significant, weakly positive trend was observed for either duration or frequency of use, but not for both. In the other three case–control studies, no consistent trend was observed and the strongest associations tended to be seen among the shorter-term or less frequent talc users.

The cohort study and four of the eight more informative case–control studies presented results on histological type of ovarian cancer. When the analysis of the cohort study was restricted to the 160 serous invasive cases, a statistically significant increase in risk of about 40% was observed. The risk increased with increasing frequency of body powder use. Risks for serous ovarian cancer were somewhat greater than those for other histological types in two of the four case–control studies in which the contrast was reported. Results for other histological types were inconclusive.

The Working Group carefully weighed the various limitations and biases that could have influenced these findings. Non-differential misclassification of talc use, given the relatively crude definitions available, would have attenuated any true association. Although the available information on potential confounders varied by study, most investigators accounted for age, oral contraceptive use and parity. In most studies, only the adjusted relative risks were presented; however, in the three studies in which both age-adjusted and fully adjusted estimates were provided, relative risks did not differ materially, suggesting minimal residual confounding.

It is possible that confounding by unrecognized risk factors may have distorted the results. One or more such factors, if they are causes of ovarian cancer and also associated in the population with perineal use of talc, could induce the appearance of an association between the use of talc and ovarian cancer where there is none. In order for such an unrecognized risk factor to induce the consistent pattern of excess risks in all of the case–control studies, it would be necessary for the factor to be associated with perineal talc use across different countries and different decades. While the range of countries and decades covered by the more informative case–control studies is not very broad, it provides some

diversity of social and cultural context and thereby reduces the likelihood of a hidden confounder.

There was a distinct pattern of excess risk discernible in all of the case-control studies when users were compared with non-users; however, methodological factors needed to be considered. First, while chance cannot be ruled out as an explanation, it seemed very unlikely to be responsible for the consistent pattern of excess risks. A second possible explanation would be recall bias, to which case-control studies may be particularly susceptible. This may have been the case if there had been widespread publicity about the possible association between the use of body powder and cancer. In such circumstances, it is possible that women who had ovarian cancer could be more likely than women who did not to remember or over-report a habit, such as body powder use, if they thought that it may have played a role in their illness. There was a flurry of publicity in the USA in the mid-1970s concerning the possible risks for cancer posed by the use of talc-based body powders. Following an industry decision to market talc powders with no asbestos, it was the opinion of the Working Group that there had not been widespread public concern about this issue, at least until very recently. Therefore, the Working Group considered it unlikely that such a bias could explain the set of consistent findings that stretch over two decades. The Working Group believed that recall bias was a possibility inherent in the case-control studies and could not be ruled out. The Working Group also considered publication and selection biases and these were not judged to have substantially influenced the pattern of findings.

The Working Group searched for documentation on the presence of known hazardous minerals in talc-based body powders. There were strong indications that these products contained quartz in the mid-1970s and still do. There were also indications that occasional small concentrations of asbestos were present in these products before the mid-1970s, but the available information was sparse, sampling methods and detection limits were not described, and the range of locations where data were available was extremely limited. As a result, the Working Group found it difficult to identify a date before which talc-based body powders contained other hazardous minerals and after which they did not, or to have confidence that this would be applicable worldwide. In addition, the epidemiological studies generally do not provide information about the years during which the female subjects were exposed. Consequently, the Working Group could not identify studies in which an uncontaminated form of talc was the only one used by study subjects. Nevertheless, the Working Group noted that, even in the most recent studies in the USA, where exposure histories may have been much less affected by hazardous contaminants of talc, the risk estimates were not different from the early studies in which the possibility of such exposure was more likely.

To evaluate the evidence on whether perineal use of talc causes an increased risk for ovarian cancer, the Working Group noted the following:

- The eight more informative case-control studies, as well as most of the less informative ones, provided overall estimates of excess risk that were remarkably consistent; seven of these eight case-control studies examined exposure-response

relationships; two provided evidence supporting such a relationship, two provided mixed evidence and three did not support an association.

- The cohort study neither supports nor strongly refutes the evidence from the case-control studies.

- Case-control studies were susceptible to recall bias which could tend to inflate risk estimates but to an unknown degree.

- All of the studies were susceptible to other potential biases which could either increase or decrease the association.

- All of the studies involved some degree of non-differential misclassification of exposure that would tend to underestimate any true underlying association.

5.3 Animal carcinogenicity data

Talc of different grades was tested for carcinogenicity in mice by inhalation exposure, intrathoracic, intraperitoneal and subcutaneous injection, in rats by inhalation exposure, intrathoracic injection, intraperitoneal injection, oral administration and intrapleural and ovarian implantation, and in hamsters by inhalation exposure and intratracheal injection.

In male and female rats exposed by inhalation to a well-defined talc, the incidence of alveolar/bronchiolar carcinoma or adenoma and carcinoma (combined) was significantly increased in female rats. The incidence of adrenal medulla pheochromocytomas (benign, malignant or complex (combined)) showed a significant positive trend and the incidence in high-dose males and females was significantly greater than that in controls. The incidence of malignant pheochromocytomas was also increased in high-dose females. The Working Group did not consider it probable that the increased incidence of pheochromocytomas was causally related to talc but, based on the experimental data available, neither could talc-related effects be excluded.

Tumour incidence was not increased following the intrapleural or intrathoracic administration of a single dose of various talcs to rats. In two studies of intraperitoneal administration in rats, no increase in the incidence of mesotheliomas was observed. No increased incidence of tumours was produced in rats in two studies of talc administered in the diet or in another study of the implantation of talc on to the ovary.

Tumour incidence was not increased in mice following the inhalation of talc in one study, the intrathoracic administration of a single dose of various talcs in another study or the administration of talc by intraperitoneal injections in three studies. A single subcutaneous injection of talc into mice did not produce local tumours.

Tumour incidence was not increased following inhalation or intratracheal administration of talc to hamsters.

5.4 Mechanistic considerations and other relevant data

Different mechanisms are probably operative in the effects of talc on the lung and pleura, depending on the route of exposure.

In humans, deposition, retention and clearance of talc have been insufficiently studied, although talc particles have been found at autopsy in the lungs of talc workers.

In humans and experimental animals, the effects of talc are dependent on the route of exposure, and the dose and properties of the talc. Talc pneumoconiosis was somewhat more prevalent and severe among miners exposed to talc containing asbestiform minerals and/or asbestos than among those exposed to talc without such contaminants. However, the role of quartz and asbestos in the observed pneumoconiosis could not be ruled out. Among drug users, intravenous injection of talc present as a filler in the drugs resulted in microembolization in a variety of organs and alterations in pulmonary function.

In animal studies, talc has been shown to cause granulomas and mild inflammation when inhaled. Observations of the effects that occurred in the lungs of rats exposed by inhalation to talc suggested that the operative mechanisms may be similar to those identified for carbon black, and talc is known to cause the release of cytokines, chemokines and growth factors from pleural mesothelial cells.

In humans, intrapleural administration of talc as a therapeutic procedure results in pleural inflammation which leads to pleural fibrosis and symphysis. Pleural fibrosis is the intended effect of intrapleural administration of talc in patients with malignant pleural effusions or pneumothorax. Animal studies suggested that extrapulmonary transport of talc following pleurodesis increases with decreasing particle size and increasing administered dose. Talc has been shown to cause apoptosis of malignant cells *in vitro*.

Perineal exposure to cosmetic talc in women is of concern because of its possible association with ovarian cancer. Several studies have been conducted in women to assess potential retrograde movement of particles through the reproductive tract to the ovaries. These have been conducted in women who were about to undergo gynaecological surgery, most of whom had diseases or complications of the reproductive tract and organs that required surgery. The findings reported in these studies may be confounded by the various levels of dysfunction in clearance from the female reproductive tract due to underlying pathologies. In addition, most of the studies had little or no further information on the use of talc products for perineal hygiene or changes in habits that may have preceded surgery. On balance, the Working Group believed that the evidence for retrograde transport of talc to the ovaries in normal women is weak. In women with impaired clearance function, some evidence of retrograde transport was found. Studies in animals (rodents, lagomorphs and non-human primates) showed no evidence of retrograde transport of talc to the ovaries.

In one study, predictors of the presence of antibodies to mucin protein were inversely related to the risk for ovarian cancer and exposure to powder containing talc.

No data were available on the genotoxic effects of exposure to talc in humans. The limited number of studies available on the genetic toxicology of talc *in vitro* gave negative results.

6. Evaluation and Rationale

Cancer in humans

There is *inadequate evidence* in humans for the carcinogenicity of inhaled talc not containing asbestos or asbestiform fibres.

There is *limited evidence* in humans for the carcinogenicity of perineal use of talc-based body powder.

Cancer in experimental animals

There is *limited evidence* in experimental animals for the carcinogenicity of talc not containing asbestos or asbestiform fibres.

Overall evaluation

Perineal use of talc-based body powder is *possibly carcinogenic to humans* (Group 3).

Inhaled talc not containing asbestos or asbestiform fibres is *not classifiable as to its carcinogenicity* (Group 3).

Rationale

In making this evaluation the Working Group considered the human and animal evidence as well as evidence regarding the potential mechanisms through which talc might cause cancer in humans.

The Working Group found little or inconsistent evidence of an increased risk for cancer in the studies of workers occupationally exposed to talc. The studies of talc miners and millers were considered to provide the best source of evidence, but no consistent pattern was seen. One study observed an excess risk for lung cancer among miners, but confounding from exposure to other carcinogens made it difficult to attribute this to talc and no excess risk was seen in millers. Other studies also found no increased cancer risk or no higher risk with increasing cumulative exposure. Overall, these results led the Working Group to conclude that there was *inadequate evidence* from epidemiological studies to assess whether inhaled talc not containing asbestos or asbestiform fibres causes cancer in humans.

For perineal use of talc-based body powder, many case-control studies of ovarian cancer found a modest, but unusually consistent, excess in risk, although the impact of bias and potential confounding could not be ruled out. In addition, the evidence regarding exposure-response was inconsistent and the one cohort study did not provide support for an association between talc use and ovarian cancer. Concern was also expressed that

exposure was defined in a variety of ways and that some substances called talc may have contained quartz and other potentially carcinogenic materials. A small number of Working Group members considered the evidence to be inadequate. Despite these reservations, the Working Group concluded that the epidemiological studies taken together provide *limited evidence* of an association between perineal use of talc-based body powder and an increased risk for ovarian cancer.

In one study of rats that inhaled talc, an excess incidence of malignant lung tumours was seen in females. The same study observed an excess incidence of pheochromocytomas in the adrenal medulla in both sexes, but the Working Group was divided as to whether these rare tumours could be attributed to exposure to talc. Other studies in rats and mice using different routes of administration did not find an excess of cancer, and two studies in rats were considered to be inadequate for evaluation. Based on the one positive study, the Working Group found that there was *limited evidence* of carcinogenicity of inhaled talc in experimental animals. There was no agreement within the Working Group as to whether the evidence on pheochromocytomas should be taken into account in the evaluation of animal data.

Exhibit W

EXHIBIT**Tuttle #30**Synergism *see* Chemical Interactions**Synthetic Vitreous Fibers****P Nony, K Scribner, and T Hesterberg**, Center for Toxicology and Environmental Health, LLC, North Little Rock, AR, USA

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- Name: Synthetic vitreous fibers
- Chemical Abstracts Service Registry Number: N/A
- Synonyms: Man-made vitreous fibers, Mineral wool, Glass fibers/wool, Refractory ceramic fibers (RCF)
- Molecular Formula: Varies
- Chemical Structure: Varies

Background

Synthetic vitreous fibers (SVFs) are inorganic fibrous materials made from a broad variety of inorganic substances with an amorphous (vitreous, i.e., noncrystalline) molecular structure. SVFs are manufactured by multiple processes involving the cooling of high-temperature inorganic oxide streams. SVFs have been arbitrarily divided into three general categories based on their composition and application: fiberglass, mineral wools, and refractory ceramic fibers (RCF); however, the recent development of 'hybrid' SVFs has made these classifications obsolete for hazard classification. The fiberglass category includes continuous glass fibers (textile fibers) and glass wools. Fiberglass products are manufactured from powdered sand and consist of silicon and aluminum oxides. The mineral wool category includes rock and slag wools. Similar to fiberglass, mineral wools are primary aluminum and silicon oxides. Rock wool is manufactured from igneous rocks, while slag wool is manufactured from slag from blast furnace steel. Refractory ceramic fibers are specialized fibers that contain a significantly higher amount of alumina than other fibers. Although RCFs are amorphous at low temperatures, they partially crystallize at higher temperatures.

SVF materials can release airborne fibers, some respirable to the lower lung, during manufacturing and installation, and many people have been occupationally exposed since the first development of SVFs in the late nineteenth century. The discovery of potential respiratory health effects of chronic asbestos exposure in the early twentieth century led to concern regarding the potential adverse health effects of chronic inhalation of SVFs. Epidemiological evidence from the post-World War II era suggested that chronic inhalation of asbestos is associated with an elevated risk of thoracic cancers, especially in asbestos workers who smoked cigarettes. In North American asbestos workers, the incidence of death from lung cancer was 4.6 times greater than the incidence among American males. An association between mesothelioma (cancer of the membranes covering the lungs (pleura), other viscera, and lining body cavities) and occupational exposure to asbestos was suggested and eventually confirmed in asbestos miners in South Africa and in retired asbestos workers.

The asbestos saga taught two important lessons: the biological effects of chronic inhalation of any dust must be examined, and the adverse effects of chronic exposure to a dust may be greatly delayed and become apparent only after studying the pulmonary health of a large population of exposed individuals. Thus, much research since has been directed toward determining what types of particles are potentially toxic and why. In the last two decades, much has been learned about the inhalation effects of SVFs. Findings have impacted the development of occupational exposure regulations and carcinogenicity classification systems for SVFs throughout the world.

Uses

SVFs have been used for thermal and acoustical insulation, liquid and gas filtration, industrial textiles, and reinforcement of other materials. Glass, rock, and slag wools are primarily used in insulating materials for homes, building, and appliances. Filament fibers have been used in plastics, cement, papers, roofing materials, and industrial fabrics, as well as for electrical purposes. Special-purpose fibers include glass fibers produced by flame attenuation for special applications such as fluid and air filtration. Electrical glass (E-glass) is a special-purpose fiberglass developed for electrical applications that has heat and water resistance. RCFs are used in insulation that requires very high temperature resistance, such as furnace insulation. The production and use of SVFs have increased over the years, as they are commonly used to replace asbestos.

Environmental Fate and Behavior

SVFs are highly persistent in the environment. While SVFs dissolve readily in aqueous solutions at certain pHs, this is more relevant to biological systems. Transportation of SVFs in the environment is governed by fiber size, and the subsequent ability to remain suspended in ambient air for extended periods of time. As such, inhalation exposure to airborne SVF is the primary health concern for environmental and occupational exposure.

Toxicokinetics

SVFs act through direct contact with lung tissue or by stimulating acute and/or chronic inflammatory responses in lung tissue. This can occur directly through generation of reactive

oxygen species (ROS), or indirectly through macrophage-mediated clearance. Important determinants of SVF toxicity are fiber size, biopersistence, and dose.

The aerodynamic diameter of an SVF determines whether it can be inhaled into the lower lung and where in the lung it will deposit. The actual diameter is much more important than length in determining the aerodynamic diameter, and relatively long fibers with very small diameters can travel with the inhaled air stream deep into the lung. Asbestos fibers as long as 200 μm have been observed in human and rat lung tissue and 40–80% of fibers with aerodynamic diameters $<1\text{ }\mu\text{m}$ that are inhaled into the human lower lung travel back out with exhaled air. Lung deposition of SVFs in rats was greatest for fibers with an aerodynamic diameter of 2 μm and most efficient in rats and humans when fiber diameter was less than 3 μm . Inhaled particles with an aerodynamic diameter $>3\text{--}4\text{ }\mu\text{m}$ tend to deposit in the upper airways and are quickly cleared to the throat by the mucociliary escalator.

While fiber diameter is a major determinant of respirability and lung deposition, fiber length affects the rate of clearance from the lower lung. In the healthy lung, if the exposure is not extreme, small non-fibrous particles and fibers shorter than 15–20 μm are presumably phagocytized and transported quickly by alveolar macrophages (AMs) to the mucociliary escalator and cleared to the throat (exceptions include lung overload, and chemically cytotoxic particles such as crystalline silica). However, fibers longer than 15–20 μm may be too long for AMs to phagocytize and transport, thus clearance of long fibers from the lower lung cannot occur until they dissolve or break transversely into fragments that are short enough to be removed. If fibers are thin, they will gain entry to the deep lung. If they are long and chemically durable, they will accumulate during chronic exposure and will remain in the lung for extended periods of time or, in the case of the very durable amphibole asbestos types (e.g., crocidolite and amosite), indefinitely. The more biopersistent the fiber, the greater its potential to exert biological effects on the lung. Biopersistent fibers may be more likely than bio-soluble fibers to be taken up by the lung epithelium and translocated into the interstitium and to the pleural space, where they would continue to cause inflammation. Thus, the more biopersistent fibers have the potential to impact a broader range of target tissues.

Mechanisms of Toxicity

When large numbers of foreign particles of any composition deposit in the airways or bronchiole-alveolar region of the lung, the initial response is irritation followed by inflammation, in which AMs play a central role. The AMs migrate to sites of dust deposition and attempt to phagocytize the particles, destroy them, or translocate them to the mucociliary escalator. Simultaneously, the phagocytes release a complex series of chemical messengers that activate and attract inflammatory cells, stimulating mucus secretion, the generation of reactive oxygen species (ROS), and release of inflammatory mediators. The cascade continues as long as the irritant particles persist, subsiding only when and if the particles are cleared from the lung.

The mechanisms of fiber-induced biological effects are believed to include the following: long, thin fibers are inhaled into the deep lung; durable, long fibers resist lung clearance and degradation; fibers are translocated into the lung interstitium and pleura fibers stimulate the cellular release of inflammatory mediators; chronic release of mediators causes tissue injury, followed by tissue repair and cell proliferation; chronic injury-repair results in fibrosis; and advancing fibrosis and chronic proliferation may contribute to carcinogenesis. Additionally, fibers may directly physically or chemically (e.g., by free radicals) induce neoplastic changes in the genetic material of the cell or act as cocarcinogens or promoters in concert with other substances such as tobacco smoke.

All of these factors are affected by the target-organ (lung) dose over time, which is determined by lung deposition (respirability) and retention of fibers. Deposition and retention are determined by fiber size and shape, and retention is additionally determined by physical and chemical durability. Fiber surface reactivity, especially in regard to the ability to generate ROS, may play a role in toxicity and genotoxicity. Impacting the potential pathogenesis are other factors that compromise pulmonary health, including previous or current disease and exposure to toxic cofactors such as cigarette smoke, dusts, vapors, or fumes.

Acute and Short-Term Toxicity

Studies examining acute toxicity of SVF exposure are limited. Most studies examine the longer term effects (lung cancer, mesothelioma) of a single or occupational exposure to SVFs, indicating that acute toxic responses are not significant. Acute exposure in animal studies caused pulmonary and pleural inflammation directly related to fiber size and exposure dose. In general, SVF exposure induces eye and upper respiratory tract irritation as well as dermal irritation often classified as 'fiberglass itch.' Respiratory tract irritation may present as sore throat, nasal congestion, laryngeal pain, and cough. These symptoms do not persist postexposure.

Chronic Toxicity

Mortality Studies: Fiberglass and Mineral Wool (Occupational Exposure)

Two major mortality studies have been conducted on fiberglass and mineral wool manufacturing workers in Europe and the United States, while a smaller study was conducted in Canada. The European study followed the mortality of 25 000 manufacturing workers in SVF factories through 1977, with a follow-up through 1982, and a final update through 1990 for most plants. The glass wool subcohort showed no elevation in mortality due to lung cancer when compared with local mortality rates, and the continuous glass filament subcohort did not show any significant elevations in mortality. The rock wool/slag wool subcohort showed an excess of lung cancer mortality (using both national and local mortality rates). However, the researchers concluded that the mesothelioma mortality incidence in the rock/slag wool subcohort (0.03%) 'may not

represent an excess.¹ Both the original study and the updated studies found no association between employment in fiberglass or mineral wool manufacturing and increased mortality from other cancers, or from nonmalignant respiratory diseases.

US researchers conducted a comprehensive review of 16 646 workers at fiberglass and mineral wool manufacturing plants, many of who had long-term occupational SVF exposure. The study indicated some small but statistically significant excesses in lung cancer mortality among the fiber workers. The respiratory cancer standard mortality ratio was higher among mineral wool workers than among glass wool and glass textile workers. However, the data were not consistent with a causal relationship, because there was no pattern of increased risk related to duration of employment or individual worker exposure. A recent update confirmed previous findings, and with additional information regarding employee smoking habits, established no significant association between fiber exposure and the earlier observed increase in respiratory disease. The study determined that the excess of lung cancer mortalities was due to smoking habits and not SVF exposure. A case-control study of mortality among employees in slag wool manufacturing plants also found no increased risk of lung cancer associated with exposure to slag wool, but did observe increased risk with increasing pack-years of cigarette smoking.

Another study examining 2557 male workers at a glass wool manufacturing plant reported a statistically significant excess in lung cancer mortality among the fiberglass workers. They concluded that the interpretation of this finding was difficult because there was no relationship between lung cancer and length of time since first exposure to the fiberglass production environment. Epidemiologists at Harvard University reviewed the various studies of fiberglass and mineral wool workers and made similar conclusions.

Morbidity Studies: Fiberglass and Mineral Wool

A morbidity study on the respiratory health of 1089 workers employed at fiberglass and mineral wool plants found the employees to be generally healthy, with no respiratory symptoms or adverse lung functions related to fiber exposure. The study was later enlarged to include over 1435 workers and included over 300 local comparison workers (who had not worked with fibers). Looking at the follow-up study as a whole, the results showed no signs of health effects due to SVF exposure in the workers.

Morbidity Studies: Refractory Ceramic Fiber

As a product manufactured for a specific niche, the estimated exposed population involved in the manufacture, distribution, installation, conversion, and end use of RCF is small. Studies showed that lung function among RCF workers was significantly reduced among males who were current or past cigarette smokers, but not among those who had never smoked. In contrast, female lung function was significantly reduced for nonsmokers but not smokers. However, the employment periods for the women were mostly quite short, and the numbers in the female subcohorts were small, especially when divided into smokers and never-smokers. A follow-up longitudinal study of a subgroup of the male

employees found no additional yearly loss in lung function among the RCF employees, probably due to lower RCF exposure in the manufacturing plants since the 1980s. Similar results were reported in a group of European RCF manufacturing workers, though the researchers concluded that cumulative exposure to RCFs may have caused airway obstruction by promoting the effects of cigarette smoke.

Chronic Inhalation Studies in Animals

Several chronic, multi-dose studies have been performed in rodents, examining the carcinogenicity potential of various SVFs, especially in regard to lung cancer and mesothelioma. Early studies in rats exposed to two types of building insulation fiberglass: JM901 and CertainTeed, showed that they induced only transient lung inflammation that disappeared after a post-exposure recovery period. None of the exposed rats developed fibrosis, and lung tumor incidence was at background levels. Conversely, very high exposure to chrysotile asbestos and crocidolite asbestos induced lung fibrosis and pulmonary tumors. Tumor incidences were 20% for chrysotile (13 lung tumors and 1 mesothelioma) and 14% for crocidolite (15 lung tumors and 1 mesothelioma). Hamsters exposed to JM901 also did not develop fibrosis or thoracic neoplasms.

Although very high exposures to chrysotile asbestos (~ 1 million f cm^{-3}) resulted in lung fibrosis, lung cancer, and a few mesotheliomas in rat inhalation studies, recent studies indicate that chrysotile is very biosoluble, having half-times of clearance from the lung between 0.3 and 11.4 days (Table 1). Furthermore, a chrysotile exposure level of 536 f cm^{-3} resulted in no lung fibrosis or any other pathological changes in rat

Table 1 Correlation of results from biopersistence and inhalation toxicity

Fiber	Biopersistence	Inhalation toxicity	
	Half-life (days)	Fibrosis	Tumors
Crocidolite asbestos	817	+	+
Amosite asbestos	418	+	+
E-glass – special-purpose fiberglass	79	+	+
RCF1 – refractory ceramic fiber	55	+	+
JM475 – special-purpose fiberglass	49	+	–
Rock wool	67	+	–
JM901 – insulation wool fiberglass	37	–	–
JM901.1 – insulation wool fiberglass	14.5	–	–
X607	9.8	–	–
CertainTeed – insulation wool fiberglass	9	–	–
Slag wool	9	–	–
Stone wool	6	–	–
Chrysotile asbestos ^a	0.3–11.4	–	ND

ND, not determined.

^aWhile studies have shown that very high exposures to chrysotile asbestos can induce fibrosis and pulmonary tumors, a 90 day inhalation study in rats exposed to 536 f cm^{-3} resulted in no fibrosis. Pulmonary tumors in lower exposures have not been determined.

Adapted from: Hesterberg, T.W., Chase, G., Axten, C., Miller, W.C., Musselman, R.P., Kamstrup, O., Hadley, J., Morscheidt, C., Bernstein, D.M., Thevenaz, P., 1998. Biopersistence of synthetic vitreous fibers and amosite asbestos in the rat lung following inhalation. *Toxicol. Appl. Pharmacol.* 151(2), 262–275.

lungs after 90 days of inhalation exposure. It has been well documented in the peer-reviewed literature that if fibrosis is not observed after 90 days of inhalation exposure to fibers, then no lung cancer or mesotheliomas will be observed after chronic inhalation to fibers for up to 3 years. Thus, one would predict that chrysotile exposures below 536 f cm^{-3} would not result in lung cancer or mesotheliomas in a rat inhalation study.

In addition to JM901, the hamster chronic inhalation study also tested a relatively durable special application fiberglass, JM475, and amosite asbestos (Table 1). During the first 12 months of exposure, amosite asbestos fibers $>20 \mu\text{m}$ accumulated in the lungs in quantities that suggested little or no clearance, whereas lung burdens of JM475 glass fiber (a durable special-purpose fiberglass) and JM901 glass fiber (an insulation wool fiberglass) plateaued at a level 10–37-fold less than that of amosite, suggesting greater clearance rates for these types of fiberglass. Although hamsters exposed to JM901 developed no permanent pulmonary or thoracic changes during the 18 month exposure and 5 week recovery periods, hamsters exposed to the more durable JM475 glass fibers developed minimal lung fibrosis and one mesothelioma (in 83 animals at risk; 1.2% tumor incidence) (Table 1). Hamsters exposed to amosite asbestos at a comparable aerosol concentration or a comparable lung dose also developed fibrosis, but earlier and more severe than that in the animals exposed to JM475. Hamsters exposed to amosite developed mesotheliomas at all doses.

In recent mineral wool studies, rats were exposed by nose-only inhalation to rock and slag wool in three concentrations for 6 h day⁻¹, 5 days week⁻¹, for 24 months. In agreement with the earlier inhalation studies of mineral wool, neither test fiber was tumorigenic. However, the rock wool-exposed rats developed minimal fibrosis. In a later chronic inhalation study also using rats, IJT stone wool, at a concentration similar to those of rock and slag wool, induced only transient lung irritation; no fibrosis was observed and the incidence of thoracic tumors was not elevated over that of air-breathing chamber controls. A fourth fiber that could be considered a hybrid between mineral wool and fiberglass, X607, was also found to be innocuous in a 2 year rat chronic inhalation study, and again demonstrated the relationship between biopersistence and pathogenicity. After chronic exposure, fibers/lung (especially long fibers) were much lower for X607 than for RCF1, demonstrating less biopersistence for X607. Chemical analysis of lung fibers confirmed the lower biopersistence of X607, in that these fibers showed rapid leaching, whereas RCF1 lung fibers did not.

Inhalation studies have also examined the carcinogenic potential of RCFs over chronic exposures. Rats and hamsters were exposed to RCF for 6 h day⁻¹ and 5 days week⁻¹, at a maximum dose of 30 mg m^{-3} for either 24 months (rats) or 18 months (hamsters). Rats were exposed to one of four different types of RCF (RCF1 (kaolin), RCF2 (zirconium), RCF3 (high purity), and RCF4 (after service)), and hamsters were exposed only to kaolin-based RCF1. Rats exposed to any of the four RCFs developed lung fibrosis, and those exposed to RCF1, 2, or 3 had elevated incidences of lung tumors (9–19%) and mesotheliomas (2–3%). Rats exposed

to RCF4 did not develop increased lung tumors (3.4%) but did have one (1.4%) mesothelioma (Table 1). Compared with RCF1, 2, and 3, RCF4 was on average shorter and thicker and resulted in lower lung burdens of fibers $>20 \mu\text{m}$. Hamsters exposed to RCF1 also developed lung fibrosis, but they developed no lung tumors and a high (41%) incidence of mesotheliomas. These studies demonstrate a striking difference between rat and hamster responses to the same test fiber. After lifetime exposure to RCF1, the tumor incidences in rats vs hamsters were 13 vs 05 for lung cancer and 1.7 vs 41% for mesothelioma, respectively. Such a lack of agreement in response raises questions regarding species-related differences and which species, if either, is representative of humans.

In a subsequent study, rats were exposed to three lower doses of RCF1: 3, 9, and 16 mg m^{-3} or to filtered air. The RCF1-exposed rats at each of these doses showed some minimal, dose-dependent lung fibrosis later in the study. RCF1 at these exposure levels did not significantly elevate lung tumor incidence. The lung tumor incidences in the fiber-exposed groups, while higher than that in the concurrent negative controls (0.8%), were well within the reported background rates of 0–8% for adenoma and 0–6% for carcinoma for F344 rats through 24 months. However, one thoracic mesothelioma was observed in the rats exposed to 9 mg m^{-3} . Considering the two rat studies of RCF1, which together included four dose groups (3, 9, 16, and 30 mg m^{-3}), the authors concluded that the fact that the RCF used in this study did not demonstrate lung carcinogenicity at 3, 9, or 16 mg m^{-3} but did at 30 mg m^{-3} is significant. The lack of carcinogenicity at lower doses implies the existence of a threshold delivered dose, below which tumors will not have time to develop within the animal's life span. However, one must not discount the occurrence of one (0.8%) mesothelioma in the 9 mg m^{-3} group and lung fibrosis in all rats in the 9 and 16 mg m^{-3} groups at 12 months and thereafter. One mesothelioma in the 16 mg m^{-3} group may not be considered statistically significant, but due to its rarity as a spontaneous occurrence in rats, it is biologically significant. Although a cause and effect relationship between the development of fibrosis and the development of tumors has not been established, the two events are closely associated, with a lag time of 9–12 months for the appearance of tumors.

Fiber Biopersistence Studies in Rodents

All of the rodent chronic inhalation studies of vitreous and asbestos fibers indicated a relationship between persistence of fibers in the lung and the severity of their biological effects. The term 'lung biopersistence' was coined to refer to the capacity of fibers to preserve their chemical and physical features over time in the lung. During lung residency, pathogenic fibers such as crocidolite or amosite asbestos demonstrated the following:

- Little or no change in chemical composition or surface morphology (suggesting no significant leaching).
- Little or no decrease in diameter or length (suggesting no significant dissolution or transverse fragmentation).

- More rapid clearance of shorter fibers than of longer fibers (suggesting preferential clearance of short fibers by AMs).

In contrast, nonpathogenic fibers, such as IT Stone wool and fiberglass building insulations, demonstrated the reverse of each of these behaviors over time in the lung:

- Compositions changed and surfaces often showed signs of erosion.
- Average fiber dimensions decreased.
- The number of long fibers/lung decreased more rapidly than the number of short fibers/lung (suggesting transverse fragmentation).

The biopersistence–pathogenicity relationship suggested that biopersistence is a key determinant of pathogenicity and might be used to assess the potential carcinogenicity of inorganic fibers. Changes in fiber numbers, chemistry, dimensions, or morphology during lung residency were more pronounced in the eight SVFs than in the two asbestos types. These changes were especially striking in the biosoluble SVFs that cleared more rapidly in the biopersistent studies and were nonpathogenic in the chronic studies (JM901, CertainTeed, slag wool, and stone wool; Table 1). Fiber toxicity was associated with fiber biopersistence in the lung and to a lesser extent with *in vitro* dissolution rate. These observations support the hypothesis that biopersistence of inorganic fibers in the lung is a strong indicator of potential toxicity and is determined in part by fiber dissolution rate.

A model of fiber degradation involving incongruent dissolution (leaching) and breakage could explain why, in the lung burdens of the less persistent fibers, long fibers tended to decline more rapidly than short fibers. In this model, transverse breakage adds to the number of short fibers while macrophage-mediated clearance subtracts from it. The chemical and morphological changes of the biosoluble SVFs observed in the lung fibers further support a model of leaching and breakage: as the more soluble constituents of the fibers leave the silica matrix, the surface becomes pitted or eroded, the depleted fiber matrix weakens and becomes increasingly susceptible to fragmentation. Thus, the biopersistence of lung fibers appears to be determined by the interactions of a number of parameters, including dissolution and leaching in biological fluids, fragmentation, and macrophage-mediated clearance.

Immunotoxicity

There are currently no studies on the potential immunotoxic effects of SVFs. While studies in inhalation exposure have shown localized immune response induction, this induction ceased upon clearance from the lung, and systemic adverse effects have not been identified.

Reproductive and Development Toxicity

There are currently no studies on the potential reproductive effects of SVFs. As the primary mechanism of exposure is

inhalation, and SVFs are not readily absorbed into the body, there is no basis for the evaluation of reproductive toxicity.

Genotoxicity

Several SVFs have been found to not be genotoxic in bacterial mutations assays. However, other *in vitro* experiments have implicated SVFs in chromosomal aberrations, morphological transformations, nuclei variation (micro and multinuclei), polyploidy, and DNA breaks and crosslinks. Several SVF types with certain bioreactivities have been shown to damage DNA through generation of ROS. However, SVFs are often less genotoxic than asbestos fibers, and their potency is mediated by their size. Currently, there are no *in vivo* studies to determine the genotoxicity of SVFs in animals.

Carcinogenicity

Little evidence of adverse health effects has been found in several large, ongoing epidemiology studies of SVF manufacturing workers. There is no consistent evidence of an association between exposure to fiberglass and the development of respiratory disease or lung cancer. Some evidence of increased incidence of respiratory disease has been associated with exposure to mineral wools, which could be a carryover from an earlier time when dust controls were not as well developed as today. Studies of RCF workers found no pulmonary fibrosis or neoplastic disease, an elevated incidence (overall, ~3%) of pleural plaques, and some possible decrements in lung function among workers that smoke or have smoked tobacco products.

Based on the chronic and subchronic studies discussed earlier, RCF and certain special-purpose SVFs are the only SVFs to have shown carcinogenicity in animal studies. As such, the International Agency for Research on Cancer (IARC) has classified RCFs and certain special-purpose SVFs as a possible human carcinogens (Group 2B), while glass wool, stone wool, slag wool, and glass fibers are considered not classifiable as to human carcinogenicity (Group 3). Similarly, the EPA has classified RCFs as a Group B2, probable human carcinogen, but has not classified other SVFs in regards to their carcinogenicity. The American Conference of Governmental Industrial Hygienists (ACGIH) classifies RCF as a probable human carcinogen, with lower classifications (confirmed animal carcinogen and not classifiable) assigned to other types of SVFs.

Clinical Management

No biomarkers of disease induced by SVFs are currently known. The chest X-ray is the most commonly used diagnostic technique for the detection of lung injuries such as neoplasms, pleural plaques, or other significant injury. However, this detection is possible only after significant injury, and is not specific to the detection of SVFs, but rather any lung injury (e.g., cigarette smoking, asbestos, and other lung-related toxicants).

Ecotoxicology

No studies have documented toxicity to nonhuman species due to environmental exposure. Since toxic studies in rodents have established lung responses, it is likely that inhalation exposures to animals and wildlife may induce similar respiratory effects.

Exposure Standards and Guidelines (Table 2)

Table 2 SVF regulatory guidelines

OSHA PEL – TWA	
^a Mineral fibers are currently only regulated as nuisance dust	
General industry	
Inert or nuisance dust	
Respirable fraction	5 mg m ⁻³
Total dust	15 mg m ⁻³
Shipyard	
Fibrous glass	
Respirable fraction	5 mg m ⁻³
Total dust	15 mg m ⁻³
Shipyard	
Mineral wool	
Respirable dust	5 mg m ⁻³
Total dust	15 mg m ⁻³
ACGIH TLV – TWA	
Synthetic vitreous fibers	
Continuous filament glass fibers ^a (A4)	1 f cm ⁻³
Continuous filament glass fibers ^b (A4)	5 mg m ⁻³
Glass wool fibers ^a (A3)	1 f cm ⁻³
Rock wool fibers ^a (A3)	1 f cm ⁻³
Slag wool fibers ^a (A3)	1 f cm ⁻³
Special-purpose glass fibers ^a (A3)	1 f cm ⁻³
Refractory ceramic fibers ^a (A2)	0.2 f cm ⁻³
NIOSH REL – TWA	
Fibrous glass dust (1977 proposal)	
Total dust	5 mg m ⁻³
Fibers with diameter equal or less than 3.5 µm, and length equal to or greater than 10 µm	3 f cm ⁻³

^aFibers longer than 5 µm; diameter less than 3 µm; aspect ratio greater than 5:1.

^bInhalable fraction.

A2 – Suspected human carcinogen; A3 – Confirmed animal carcinogen with unknown relevance to humans; A4 – Not classifiable as a human carcinogen.

See also: Asbestos; Respiratory Tract Toxicology.

Further Reading

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- Rogers, R.A., Antonini, J.M., Brismar, H., et al., 1999. In situ microscopic analysis of asbestos and synthetic vitreous fibers retained in hamster lungs following inhalation. *Environ. Health Perspect.* 107, 367–375.
- Utell, M.J., Maxim, L.D., 2010. Refractory ceramic fiber (RCF) toxicity and epidemiology: a review. *Inhal. Toxicol.* 22, 500–521.

Relevant Websites

- <http://www.atsdr.cdc.gov> – Agency for Toxic Substances and Disease Registry. Toxicological Profile for Synthetic Vitreous Fibers.
- <http://www.iarc.fr> – Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, vol. 81 – Man Made Vitreous Fibers.

Exhibit X

GHASSAN M. SAED, PH.D.

Associate Professor with Tenure (Research)

OFFICE ADDRESS: The C.S. Mott Center for Human Growth and Development
Department of Obstetrics and Gynecology
275 East Hancock Avenue
Detroit, MI 48201

OFFICE TELEPHONE NUMBER: (313) 577-5433

OFFICE FAX NUMBER: (313) 577-8554

EMAIL ADDRESS: g.saed@wayne.edu

EDUCATION:

Ph.D. in Molecular Biology 1983–1986
University of Essex, Colchester, England, United Kingdom

B.S. in Biochemistry 1979–1982
King Saud University, Riyadh, Saudi Arabia

POSTGRADUATE TRAINING:

Fellowship in Immunopathology, University of Michigan, Ann Arbor, MI 1992–1993
Fellowship in Molecular Biology, Henry Ford Hospital, Detroit, MI 1988–1990

FACULTY APPOINTMENTS:

Adjunct Associate Professor, Department of Oncology, Karmanos Cancer Institute, Detroit Medical Center/Wayne State University School of Medicine, Detroit, MI 2017–Present

Director, Ovarian Cancer Biology Research, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI 2009–Present

Scientific Member, Karmanos Cancer Institute, Molecular Biology and Genetics Program, Wayne State University School of Medicine, Detroit, MI 2008–Present

Member of Tumor Biology and Microenvironment Program, Karmanos Cancer Institute, Detroit, MI 2007–Present

Associate Professor (secondary), Department of Physiology, Wayne State University School of Medicine, Detroit, MI 2008–Present

Associate Professor (primary), Department of Obstetrics and Gynecology, 2007–Present

Wayne State University School of Medicine, Detroit, MI

Tenure, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI	2007–Present
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Associate Status, Department of Anatomy/Cell Biology, Wayne State University School of Medicine, Detroit, MI	2003–Present
--	--------------

Tenure Track, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI	2001–2007
---	-----------

Assistant Professor, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI	1998–2007
--	-----------

HOSPITAL OR OTHER PROFESSIONAL:

Senior Investigator, Center for Biomedical Research, Oakland University, Rochester, MI	1997–1998
--	-----------

Adjunct Associate Professor, Department of Chemistry, Oakland University, Rochester, MI	1996–2004
---	-----------

Bioscientific Staff Investigator, Dermatology Department, Henry Ford Hospital, Detroit, MI	1995–1998
--	-----------

Associate Staff Investigator, Department of Dermatology, Henry Ford Hospital, Detroit, MI	1993–1994
---	-----------

Special Lecturer, Department of Chemistry, Oakland University, Rochester, MI	1991–1996
--	-----------

Assistant Staff Investigator, Hypertension Research, Henry Ford Hospital, Detroit, MI	1990–1992
---	-----------

Technical Manager, Pharmaceutical Company, Riyadh, Saudi Arabia	1987–1988
---	-----------

Research Assistant, Biochemistry Department, King Saud University, Riyadh, Saudi Arabia	1982–1983
---	-----------

MAJOR PROFESSIONAL SOCIETIES

Associate Member, Society for Gynecologic Oncology	2017–Present
--	--------------

Member, American Association of Cancer Research	2008–Present
---	--------------

Member, American Federation of Clinical Research	2009–Present
--	--------------

Member, American Society for Reproductive Medicine	1998–Present
--	--------------

Member, Society for Reproductive Investigation	1998–Present
--	--------------

Member, American Association of University Professors	1996–Present
---	--------------

Member, American Chemical Society	1991–2014
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National Research Council of the United Kingdom	1985–1986
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Medical Research Council of the United Kingdom	1984–1998
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HONORS/AWARDS:

Star Award

2017

73rd American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo

This award recognizes members who have presented during at least nine of the ASRM Annual Meetings from the years 2007-2016. Presentations may include Congress courses and/or seminars, Scientific Program symposia, posters, and/or oral presentation of abstracts. 234 awardees

Award for Research

2017

Awarded to Nicole King, PhD, Postdoctoral Fellow in the laboratory of Dr. Ghassan Saed

73rd American Society for Reproductive Medicine (ASRM Scientific Congress & Expo

The purpose of this award is to recognize outstanding research conducted by individuals in training under the "Reproductive Surgery" category. He/she is a presenting first author, and a medical student, resident, fellow, or undergraduate, graduate, or postdoctoral student. Three awardees

Star Award

2016

72nd American Society for Reproductive Medicine (ASRM) Scientific Congress & Expo

This award recognizes members who have presented during at least nine of the ASRM Annual Meetings from the years 2007-2015. Presentations may include Congress courses and or seminars, Scientific Program symposia, posters, and/or oral presentation of abstracts. ~235 awardees

Excellence in Biomedical Research

2015

Global Medical Discovery Series

Key Scientific Article for peer-reviewed publication entitled: "Sox2 Gene Amplification Significantly Impacts Overall Survival in Serous Epithelial Ovarian Cancer." Reproductive Sciences 22(1):38-46, 2015. Epub July 18, 2014. One awardee

Star Award

2013

69th American Society for Reproductive Medicine Annual Meeting (ASRM)

This award recognizes members who have presented during at least nine of the ASRM Annual Meetings from the years 2007-2012. Presentations may include Congress courses and/or seminars, Scientific Program symposia, posters, and/or oral presentation of abstracts. ~235 awardees

Star Award

2011

67th American Society for Reproductive Medicine (ASRM) Annual Meeting

This award recognizes members who have presented during at least nine Of the ASRM Annual Meetings from the years 2007-2010. Presentations may include Congress courses and/or seminars, Scientific Program symposia, posters, and/or oral presentation of abstracts. ~235 awardees

President's Award for Excellence in Teaching Wayne State University School of Medicine <i>This award is in recognition for outstanding faculty who have made contributions to teaching at WSU to an exceptionally high degree, demonstrate comprehensive knowledge of their subject, superior classroom performance, and high educational standards; communicate their subject matter accurately, clearly, and effectively; generate enthusiasm and respect for learning; motivate their students to excel; and are accessible to students; innovative instructional practices, impact on teaching at WSU, and contributions to advancing teaching in their field.</i>	2009
Finalist Paper 62 nd American Society for Reproductive Medicine (ASRM) Annual Meeting <i>One awardee</i>	2006
Prize Paper Candidate Conjoint 61 st American Society for Reproductive Medicine (ASRM) Annual Meeting and 51 st Canadian Fertility and Andrology Society Annual Meeting <i>One awardee</i>	2005
Finalist Paper 61 st American Society for Reproductive Medicine (ASRM) Annual Meeting <i>One awardee</i>	2005
Finalist Paper Society of Reproductive Endocrinology and Infertility (SREI) Annual Meeting <i>One awardee</i>	2003
Finalist Paper, Basic Science 19 th European Society of Human Reproduction and Embryology (ESHRE) Annual Meeting <i>One awardee</i>	2003
Award Paper 58 th Society of Reproductive Surgeons (SRS) Scientific Program	2000
Finalist Paper Society of Reproductive Endocrinology and Infertility (SREI) Annual Meeting <i>One awardee</i>	2000
Award Paper 52 nd Society of Reproductive Surgeons (SRS) Scientific Program	1998
Outstanding Professor of the Year Award Golden Key National Society, Oakland University Chapter, Rochester, MI <i>One awardee</i>	1996–1997

SERVICE:

Wayne State University

Departmental/Divisional

Chairperson, Organizing Committee, 2017 Joint Annual Reproductive Sciences Retreat, Departments of Obstetrics and Gynecology, Wayne State University School of Medicine and University of Toronto; and The Michigan Alliance for Reproductive Technologies and Sciences (MARTS) Annual Meeting at Wayne State University	2017
Faculty Mentor, NIH/NICHD Women's Reproductive Health Research (WRHR) Scholar Program, Department of Obstetrics and Gynecology	2012–2016
Faculty Associate, Fulbright Visiting Senior Scholar Award recipient Dr. Iyad Ali, Department of Obstetrics and Gynecology	2012–2014
Member, Selective Salary Committee, Department of Obstetrics and Gynecology	2012–Present
Member, Promotion and Tenure Committee, Department of Obstetrics and Gynecology	2012–Present
Chairperson, C.S. Mott Center Seminar Series Committee, Department of Obstetrics and Gynecology	1998–Present
Chairperson, Basic Research Endocrine Fellows Training Committee, Department of Obstetrics and Gynecology	1998–2014
Member, Reproductive Endocrinology and Infertility Fellowship Selection Committee, Department of Obstetrics and Gynecology	1998–Present

School of Medicine

Member, Strategic Research Initiative Grant Review (SRIG) Committee, Karmanos Cancer Institute	2013–2014
Member, PhD Committee for Batoul Abdullah, PhD Candidate, Center for Molecular Medicine and Genetics, Wayne State University	2012–2016
Member, PhD Committee for Jimmy Belotte, MD, PhD Candidate, Department of Physiology and Reproductive Sciences, Department of Obstetrics and Gynecology, Wayne State University	2012–2016
Faculty, Reproductive Sciences Graduate Program, Department of Physiology, Wayne State University	2012–2016
Member, Search Committee for a candidate selection for a joint appointment in Departments of Psychology and Obstetrics & Gynecology in the field of Psychopharmacology	2003–2005

Affiliate Medical Organizations

Member, Karmanos Cancer Institute, Molecular Biology and Genetics Program, Detroit, MI	2008–Present
--	--------------

Member of Tumor Biology and Microenvironment Program, Karmanos Cancer Institute, Detroit, MI	2007–Present
--	--------------

Professional

President, National Arab American Medical Association, Michigan Chapter, Troy, MI	2017–Present
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Judge, American Society for Reproductive Medicine (ASRM) Abstract Selection Committee, Birmingham, AL	2015–Present
---	--------------

President, National Arab American Medical Association, Michigan Chapter, Troy, MI	2014–2015
---	-----------

Board Member, National Arab American Medical Association, Michigan Chapter, Troy, MI	2009–Present
--	--------------

Judge, Poster Finals Prize Committee, 2002 Annual Meeting of the American Society for Reproductive Medicine (ASRM), Birmingham, AL	2002–2003
--	-----------

Community

Biohazard and Safety Committee, Henry Ford Hospital, Detroit, MI	1996–1998
--	-----------

Radioisotope Safety Committee, Henry Ford Hospital, Detroit, MI	1996–1998
---	-----------

Journal Club Committee, Department of Dermatology, Henry Ford Hospital, Detroit, MI	1994–1998
---	-----------

Basic Research Training Committee, Department of Dermatology, Henry Ford Hospital, Detroit, MI	1994–1998
--	-----------

Animal Care Committee, Henry Ford Hospital, Detroit, MI	1993–1996
---	-----------

Consulting

Consultant, Molecular Biologic Testing, DS Biotech, Detroit, MI	2013–Present
---	--------------

Consultant, Application of Cyclooxygenase-2 in the Treatment of Ovarian Cancer, Pfizer Pharmaceuticals, Rochester, MI	2002
---	------

Consultant, Technical expertise in developing molecular probes and markers, Oxford Biomedical Research, Oxford, MI	1991–1998
--	-----------

Scholarly Service

Grant Review Committees

Member, Scientific Review Committee, Ethel F. Donoghue Women's Health 2004
Investigator Program, Yale University, New Haven, CT

Service for Peer-Reviewed Journals Editorship

Editorial Board Membership:

Editor-in-Chief, Gynecology and Obstetrics Research-Open Journal 2015–Present

Review of Manuscripts and Chapters:

Journal of Cellular and Molecular Medicine	2015–Present
Systems Biology in Reproductive Medicine	2013–Present
Journal of Assisted Reproduction and Genetics	2013–Present
Journal of Reproductive Science	2012–Present
European Journal of Obstetrics & Gynecology and Reproductive Biology	2009
Gastroenterology	2007
Houghton Mifflin Company, College Division	2003
American Gynecological and Obstetrical Society	2003
Oncogenes	2003
Fertility and Sterility	2001–Present
Wound Repair and Regeneration	2000–Present
Journal of Cytokine Research	1998–2000

TEACHING

Teaching at Wayne State University

Undergraduate Students

Instructor. Department of Biological Sciences – BIO 3990: Undergraduate course primarily for biology majors who wish to continue in a field beyond that covered in regular courses under the direction of Biological Sciences faculty.

Instructor and Advisor. Department of Physiology – PSL 5010: Undergraduate course involving student participation in laboratory research in the physiological sciences under the supervision of a departmental faculty advisor.

This course involves an introduction to experimental protocol and current related scientific literature.

Advisor. Department of Biological Sciences – BIO 6990: Undergraduate course for honors students involving student participation in laboratory research in the physiological sciences under the supervision of a departmental faculty advisor.

Graduate Students

Instructor. Interdisciplinary Biomedical Sciences – IBS 7060: Biomedical Endocrine and Reproductive Systems Development.

This course is for graduate students within the Ph.D. Program in Anatomy and Cell Biology of which has the aim of providing a broad based knowledge of the important areas of biomedical research.

Instructor. Department of Physiology with Concentration in the Reproductive Sciences Program (PhD) – RPS 7350: Biomolecular Techniques: From Genes to Protein

Instructor. Department of Physiology with Concentration in the Reproductive Sciences Program (PhD), Principles of Reproductive Biology – PSL 7690: Cancers in Reproductive Organs/ Journal Club.

This lecture explains the impact of cancer in women; to discuss the epidemiology, risk factors, screening modalities and preventative strategies of gynecologic cancers and the role of stem cells.

Instructor. Current Research Topics in the Reproductive Sciences – PSL 7775: Molecular Mechanisms of Postoperative Adhesions.

This course is for graduate students within the Ph.D. Program in Physiology with Concentration in the Reproductive Sciences of which covers current research topics in reproductive sciences. The Program itself incorporates the teaching, research and physical resources of both the Physiology and the Obstetrics and Gynecology Departments, offering interdisciplinary doctoral training in a clinical environment in the reproductive sciences. The primary academic focus engages teaching and research training in reproduction and development, with an emphasis on the following: developmental biology, perinatal biology, reproductive endocrinology, reproductive genetics, toxicology/teratology and molecular biology including genomics, proteomics, and bioinformatics. Dissertation research is under the mentorship of Obstetrics and Gynecology basic science graduate faculty.

Advisor and Mentor. Current Research Topics in the Reproductive Sciences – PSL 7996: Arranged Research.

This course is for the graduate students within the “Ph.D. Program in Physiology with Concentration in the Reproductive Sciences” (as described in PSL 7775) which covers graduate level experiences in research techniques. It is required that special research topics, within specified areas, be agreed upon between individual faculty members and students.

Advisor and Mentor. Doctoral Candidate Status I-IV – PSL 9991, 9992, 9993, 9994: Thesis/Dissertation Research and Design.

This course is for the graduate students within the “Ph.D. Program in Physiology with Concentration in the Reproductive Sciences” (as described in PSL 7775). Required in consecutive academic-year semesters following advancement to Ph.D. candidacy status I through IV.

Advisor and Mentor. Doctoral Candidate Dissertation Research and Direction – PSL 9995: Candidate Maintenance Status.

This course is for the graduate students within the “Ph.D. Program in Physiology with Concentration in the Reproductive Sciences” as described above in PSL 7775. Required after completion of 30 credits in PSL 9991-9994.

Director. Summer Reproductive Technology Course. The CS Mott Center for Human Growth and Development, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, 2014-2015.

The course design is to allow for Reproductive Endocrinology and Infertility/Medical Genetics fellows, as well as graduate students to become familiar with laboratory techniques in the reproductive sciences. The graduate students will acquire a thorough understanding of the

theory and special methodology utilized to perform techniques indicative of reproductive endocrinology and infertility.

Lecturer. Laboratory Techniques. Summer Reproductive Technology Course. The CS Mott Center for Human Growth and Development, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, 2014.

This lecture explains the various laboratory techniques, and their limitations, as applied to the reproductive sciences.

Lecturer. Molecular Biological Procedures. Summer Reproductive Technology Course. The CS Mott Center for Human Growth and Development, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, 2015.

This lecture explains the various laboratory techniques, and their limitations, as applied to the reproductive sciences.

Residents and Fellows

Director. Summer Reproductive Technology Course. The CS Mott Center for Human Growth and Development, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, 2014-2015.

The course design is to allow for Reproductive Endocrinology and Infertility/Medical Genetics fellows, as well as graduate students to become familiar with laboratory techniques in the reproductive sciences. The fellows will acquire a thorough understanding of the theory and special methodology utilized to perform techniques indicative of reproductive endocrinology and infertility.

Instructor. PCR Technique: Concept and Clinical Application Course. The CS Mott Center for Human Growth and Development, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, 2012-Present.

This course is designed to allow departmental residents, fellows, Reproductive Endocrinology and Infertility/Medical Genetics fellows, and interested graduate students (within the C.S. Mott Center) to become familiar with the PCR technique and how to use it effectively within the laboratory.

Teaching at Other Institutions

Undergraduate Students

Adjunct Associate Professor. Taught two undergraduate courses, CHM104 "Introduction to Chemical Principles" and CHM201 "Introduction to Organic and Biological Chemistry" for nursing and health sciences students at the Department of Chemistry, Oakland University, Rochester, MI, 1991-2004.

Graduate Students

Instructor. Four-day workshop: PCR Techniques, Concepts and Applications. Howard Hughes Research Program, Oakland University, Rochester, MI, May 19-22, 1998.

This workshop was for graduate, postdoctoral, laboratory research personnel, and faculty within the field of science and research.

Instructor. Taught a graduate course CHM554 "Molecular Biology and Biotechnology" at the Department of Chemistry, Oakland University, Rochester, MI, 1995-1998.

Instructor. Biotechnology: From Genes to Proteins. Department of Dermatology, Oakland University, Rochester, MI, 1993-1998.

This course was part of the Research Training in Biotechnology Program postgraduate curriculum for residents and fellows to utilize state-of-the-art molecular technology techniques to answer questions related to molecular pathogenesis of skin diseases such as skin cancer, fibrosis and wound healing.

Teaching Assistant. Introduction to Chemical Principles. Department of Chemistry, University of Essex, Colchester, England, United Kingdom, 1987-1988.

Residents and Fellows

Instructor and Laboratory Advisor. Biotechnology Research Training. Department of Dermatology, Oakland University, Rochester, MI, 1993-1998.

This program trained dermatology residents to utilize state-of-the-art molecular technology techniques to answer questions related to molecular pathogenesis of skin diseases such as skin cancer, fibrosis and wound healing.

Mentorship

Mentor on research projects related to endometriosis, postoperative adhesions, and ovarian cancer to the Department of Obstetrics and Gynecology past and present undergraduate and graduate students, residents, clinical and postgraduate fellows, scholars, faculty, and research technicians, assistants and associates.

Undergraduate Students:

Yousif Abbiss; Newaj Abdullah; Dana Abufarha, Shadi Abuolba Ahmad [awarded the 2007 Wayne State University School of Medicine Undergraduate Research Scholarship Award]; Ali Alarab; Radi Al-Dasouqi; Danna Al-Hadidi; Jeremy Berman; Chelsea Fortin; Ellory Greenberg; Waseem Imann; Shucni Jain; Marisa Karcz; Hadil Katato; Reem Khazaal; Yanamandra Krishnakant; Wasfeh Musheinish; Bailey Neubauer; Osama Nusrat; Tessy Oommen; Norman Orabi; Alex Papadellis; Sonica Rehan; James Waleke [WSU School of Medicine 2004 graduate]; Rani Yaldo, Yousif Younan; Nabaa Zalzal; and Xuping (Sherry) Zhu.

Graduate:

Osama Nusrat, MD (Master/past): Nusrat O, Belotte J, Fletcher NM, Memaj I, Saed MG, Diamond MP, **Saed GM**. The role of angiogenesis in the persistence of chemoresistance in epithelial ovarian cancer. Reproductive Sciences 23(11):1484-1492, 2016. PMID: 27122375

Batoul Abdullah, PhD: Abdallah BY, Horne SD, Stevens JB, Liu G, Ying AY, Vanderhyden B, Krawetz SK, Gorelick R, Heng HH (2013). Single cell heterogeneity: Why unstable genomes are incompatible with average profiles. Cell Cycle 12:3640-3649, 2013. PMID: 24091732 PMCID: PMC3903715

Jimmy Belotte, MD, PhD: Belotte J, Fletcher NM, Saed MG, Abusamaan MS, Dyson G, Diamond MP, **Saed GM**. A single nucleotide polymorphism in catalase is strongly associated

with ovarian cancer survival. PLoS One 10(8):e0135739, 2015. eCollection 2015. PMID: 26301412 PMCID: PMC4547699

Nicole Fletcher-King, PhD: Fletcher NM, Belotte J, Saed MG, Memaj I, Diamond MP, Morris RT, **Saed GM**. Specific point mutations in key redox enzymes are associated with chemoresistance in epithelial ovarian cancer. Free Radical Biology and Medicine 102:122-132, 2017. PMID: 27890641

Jennell White, PhD: White JC, Jiang ZL, Diamond MP, **Saed GM**. Macrophages induce the adhesion phenotype in normal peritoneal fibroblasts. Fertility and Sterility 96(3):758-763.e3, 2011. Epub July 27, 2011. PMID: 21794857

Residents

Drs. (MD) Zeynep Alpay, Dana Ambler, Tarek Dbouk, Eslam Elhammady, and Valerie Shavell.

Clinical and Postgraduate Fellows:

Drs. (MD) Mazen Abdallah, Awoniyi Awonuga [faculty], Jashoma Banerjee, Alan Bolnick, Jay Bolnick, Subodhsingh Chauhan, Laura Detti, Michael Freeman, April Gago, Roohi Jeelani, Sana Khan, Mohamed Mitwally, Valerie Shavell, Mili Thakur, Rahi Victory, and Terri Woodard; and Christopher Bryant, MD, Associate Professor, Division of Gynecologic Oncology (past faculty).

Of note, the aforementioned have participated in premier annual scientific meetings of the American Society for Reproductive Medicine, Society for Free Radical Biology and Medicine, Society for Reproductive Investigation, and American College of Obstetrics and Gynecology, just to name a few, as well as publishing their many scientific achievements (articles and abstracts) in preeminent peer-reviewed journals (see Publications section).

Acknowledgement: Michael Freeman, MD [past fellow], was awarded a \$20,000 research grant from the American Gynecologic and Obstetrical Society (AGOS) during his fellowship [1999-2002]. Alan Bolnick, MD and Sana Khan, MD [past fellows, 2013-2016] were each awarded from the Pacific Coast Reproductive Society, the 2015 Travel Award, as well as Roohi Jeelani, MD and Mili Thakur, MD [past fellows, 2015-2017 and 2014-2017, respectively] who were each awarded the 2016 Travel Award. These AGOS travel awards paid for registration to the annual meeting, course fees, and all travel expenses incurred.

Lastly, Mili Thakur, MD [past fellow, 2014-2017] of the combined Reproductive Endocrinology and Infertility and Medical Genetics Fellowship program (the only one of its kind in the country), was the recipient of the 2016 Pfizer-SRI (Society for Reproductive Investigation), President's Presenter's Award. This award for given to Mili for her abstract entitled, "*Galactose and Its Metabolites Deteriorate Metaphase II Mouse Oocyte Quality through a Mechanism that Involves the Generation of Reactive Oxidative Species, Mitochondrial Dysfunction and Apoptosis.*" The President's Presenter's Award is given in recognition of the 25 most meritorious abstracts (either poster or oral presentation) submitted by individuals still in training. Dr. Thakur received this prestigious award at the 63rd Annual Meeting of the Society for Reproductive Investigation, Montreal, Quebec, Canada, in March of 2016.

Scholars

Iyad Ali, PhD: Assistant Professor of Biochemistry, Faculty of Medicine and Health Sciences, An-Najah National University, Nablus, Palestine; visiting Fulbright Arab Fund Fellowship Scholar in the laboratories of Drs. Husam Abu-Soud and Ghassan Saed, Division of Reproductive

Endocrinology and Infertility, Department of Obstetrics and Gynecology, Wayne State University School of Medicine.

Awoniyi Awonuga, MD: Associate Professor, Women's Reproductive Health Research (WRHR) Scholar, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, Wayne State University School of Medicine. Citation: Awonuga AO, Belotte J, Abuanzeh S, Fletcher NM, Diamond MP, **Saed GM**. Advances in the pathogenesis of adhesion development: the role of oxidative stress. *Reproductive Sciences* 21(7):823-836, 2014. Epub February 11, 2014. Review. PMID: 24520085 PMCID: PMC4107571

Jimmy Belotte, MD, PhD: Assistant Professor, Women's Reproductive Health Research (WRHR) Scholar, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, Wayne State University School of Medicine. Citation: *Belotte J, *Fletcher NM, *Alexis M, Morris RT, Munkarah AR, Diamond MP, **Saed GM**. Sox2 gene amplification significantly influences overall survival in serous epithelial ovarian cancer. *Reproductive Sciences* 22(1):38-46, 2015. Epub July 18, 2014. PMID: 25038052 PMCID: PMC4275450

Lylia Fahmy, MD: Clinical Instructor, Women's Reproductive Health Research (WRHR) Scholar, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, Wayne State University School of Medicine. Thesis: Effect of Ovarian Hormones on Adhesion Development. 2005.

Faculty

Mentor of current and past Obstetrics and Gynecology clinical faculty through collaborations on research projects and grant submissions. Faculty members are as follows: Awoniyi Awonuga, MD, Professor, Division of Reproductive Endocrinology and Infertility and Women's Reproductive Health Research (WRHR) Scholar (training completed December 2015); Jimmy Belotte, MD, Associate Professor, Division of Gynecology, Women's Reproductive Health Research (WRHR) Scholar, (training completed September 2016 with PhD); Lylia Fahmy, MD, past Clinical Instructor, Division of Reproductive Endocrinology and Infertility, Women's Reproductive Health Research (WRHR) Scholar, (training completed 2005); and Peter Baumann, MD, Associate Professor, Division of Gynecology (retired).

I have also been instrumental to key professional presentations at local, national, and international conferences by our past and present senior faculty members of the Obstetrics and Gynecology Department. They are as follows: Adnan Munkarah, MD, Professor and Director, Division of Gynecologic Oncology; Bernard Gonik, MD, Professor, Division of Maternal and Fetal Medicine; Jay Berman, MD, Associate Professor and Associate Chair, Department of Obstetrics and Gynecology and Director, Division of Gynecology; John Malone, Jr, MD, Professor and past Chair, Department of Obstetrics and Gynecology (deceased); Kamran Moghissi, MD, Professor Emeritus, past Chair Emeritus, Department of Obstetrics and Gynecology, past Director, Division of Reproductive Endocrinology and Infertility, and past Director, CS Mott Center for Human Growth and Development (retired); and Michael Diamond, MD, Professor, past Associate Chair, Department of Obstetrics and Gynecology, past Director, Division of Reproductive Endocrinology and Infertility, and past Assistant Dean of Clinical and Translational Research, Wayne State University School of Medicine (now at Georgia Regents University, Augusta, GA).

Research Associates/Assistants/Technicians

In the laboratory of Dr. Ghassan Saed: Drs. (PhD) Boytcho Boytchev, Semira Galijasevic, Zhongliang (John) Jiang, MD, Hong Lu, Qui Lu, Gheorghe Proteasa, Natalie Rizk, Rona Wang, MD, and Ming Zhao, MD; Danielle Hall, BS, Nicole Fletcher-King, BS, MS, and Manal Omar, BS.
Essays/Theses/Dissertations Directed

Name: Osama Nusrat, MD (Master Degree/past), Department of Physiology and Reproductive Sciences (2015-2017), Wayne State University School of Medicine, Detroit, MI.

Dissertation Title: The Role of Angiogenesis in the Persistence of Chemoresistance in Epithelial Ovarian Cancer

Date Awarded: September 2017

Current Status: Resident, Department of Internal Medicine, University of Arizona College of Medicine, Tucson, AZ

Name: Jimmy Belotte, MD, PhD, Department of Physiology in the Reproductive Sciences Concentration (2012-2016); and Women's Reproductive Health Research (WRHR) Scholar, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI

Dissertation Title: The Role of Oxidative Stress in the Establishment of Resistance to Cisplatin in Epithelial Ovarian Cancer Cells

Date Awarded: September 14, 2016 and WRHR training completed September 14, 2016

Current Status: Associate Professor, Division of Gynecology, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI

Name: Batoul Abdullah, PhD, Department of Physiology in the Center for Molecular Medicine and Genetics Concentration (2012-2016), Wayne State University School of Medicine, Detroit, MI

Dissertation Title: Fuzzy Inheritance: A Novel Form of Somatic Cell Inheritance that Regulates Cell Population Heterogeneity

Date Awarded: 2016

Current Status: Postdoctoral Fellow in the laboratory of Henry (Hong-Qiang) Heng, PhD, Center for Molecular Medicine & Genetics and Pathology, Wayne State University School of Medicine, Detroit, MI

Name: Awoniyi Awonuga, MD, Women's Reproductive Health Research (WRHR) Scholar, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI

Thesis Title: Oxidative Stress in the Pathogenesis of Post-Operative Adhesions

Training Completed: December 2015

Current Status: Professor and Interim Director, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI

Name: Nicole Fletcher-King, PhD, Department of Physiology in the Reproductive Sciences Concentration Program (2008-2013), Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI

Dissertation Title: The Role of Oxidative Stress in the Pathogenesis of Epithelial Ovarian Cancer

Date Awarded: September 2013

Current Status: Postdoctoral Fellow in the laboratory of Ghassan M Saed, PhD, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, CS Mott Center for Human Growth and Development, Wayne State University School of Medicine, Detroit, MI

Name: Jennell White, PhD, Department of Physiology in the Reproductive Sciences Concentration Program (2000-2011), Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI

Dissertation Title: The Potential Role of Innate Immunity in the Pathogenesis of Postoperative Adhesions

Date Awarded: September 2011

Current Status: Postdoctoral Fellow, Department of Pediatrics, Wayne State University School of Medicine, Detroit, MI

Name: Lylia Fahmy, MD, Women's Reproductive Health Research (WRHR) Scholar, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI

Thesis Title: Effect of Ovarian Hormones on Adhesion Development

Date Completed: September 2005

Current Status: Associate Professor, Department of Obstetrics and Gynecology, University of Nebraska Medical Center, Omaha, NB

Course or Curriculum Development

Originator and Director. Summer Reproductive Technology Course. 2014
This course design is to allow for Reproductive Endocrinology and Infertility/Medical Genetics fellows, as well as graduate students, to become

familiar with all aspects of laboratory techniques within the field of reproductive sciences. Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, The C.S. Mott Center for Human Growth and Development, Wayne State University School of Medicine, Detroit, MI.

- Course Director. Reproductive Sciences Concentration – RPS 7350: 2006
Biomolecular Techniques: From Genes to Protein.
This course design is specifically for graduate students enrolled in the PhD Program in Physiology with Concentration in the Reproductive Sciences, as part of their curriculum. This is an integrated PhD program incorporating the teaching, research, and physical resources of two departments -- Physiology and Obstetrics & Gynecology at Wayne State University School of Medicine, Detroit, MI.
- Organizer. Four-day workshop (May 19-22): PCR Techniques, Concepts, 1998
and Applications.
Workshop developed for undergraduates, graduates, postdoctoral, laboratory personnel, and faculty studying and/or working within the field of science and research. Sponsored by the Howard Hughes Research Program of Oakland University, Rochester, MI.
- Designer. Introduction to Molecular Cloning. 1996
Course designed to teach techniques for characterization and manipulation of DNA and RNA from the basis of modern biomedical research. Coursework pertinent towards medical residents and fellows at the Henry Ford Hospital, Detroit, MI, and graduate students at Oakland University, Rochester, MI.
- Designer. Research Training in Biotechnology. 1993
This program trained Department of Dermatology residents and fellows to utilize state-of-the-art molecular technology techniques to answer questions related to molecular pathogenesis of skin diseases such as skin cancer, fibrosis and wound healing at Henry Ford Hospital, Detroit. MI. This training ended in 1998.
- Course Director. I have participated in developing the course, Introduction to 1991–2004
Chemical Principles (CHM 104) to meet general education requirements. CHM 104 satisfies the university general education requirement in natural science and technology (NST). The learning outcomes for NST courses state that the student will demonstrate knowledge of major concepts from natural science or technology, including developing and testing of hypotheses, drawing conclusions, and reporting of findings through some laboratory experience or an effective substitute. This course taught at Oakland University, Rochester, MI.
- Designer. Laboratory course. I was actively involved in developing and 1991–2004
instructing two laboratory sections for CHM 104. Students learned how to evaluate sources of information in science or technology. Developed at Oakland University, Rochester, MI
- Designer. I developed and taught CHM 104 and CHM 201 to nursing students 2005–2010

on-line (a web-based instruction). I designed courses to satisfy the university general education requirement in natural science and technology (NST). For this, I utilized and implemented the virtual chemistry laboratory experience to be an integral part of this course. Developed at Oakland University, Rochester, MI,

GRANTS, CONTRACTS, AND OTHER FUNDING:

Active National/International Grants and Contracts

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: "Novel Biomarkers for Early Detection of Ovarian Cancer." The project's design is to identify key markers of oxidative stress that have the potential to serve as screening tools for ovarian cancer and may play a role in the acquisition of chemoresistance.
Source: Prevent Cancer Foundation, Postdoctoral Fellowship Grant
Date: 01/01/16 – 12/31/18
Total Direct Costs: \$80,000

Role: Principal Investigator, Percent Effort: 5%
Title: "Elucidation of Cellular Mechanisms of Evitar of Post-Operative Fibrosis."
Source: Temple Therapeutics, 25S8P1
Date: 04/01/17 – 05/31/18
Total Direct Costs: \$100,000

Pending National/International Grants and Contracts

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: "Novel Mechanism of Apoptosis in Chemoresistant Ovarian Cancer Cells." To determine whether chemoresistance in ovarian cancer manifests decreased apoptosis through enhanced s-nitrosylation of caspase-3 mechanism which can, thereby, be reversed by DCA.
Source: American Association for Cancer Research (AACR)
Date: 07/01/17 – 06/30/19
Total Direct Costs: \$100,000

Role: Principal Investigator, Percent Effort: 30%
Title: "Identification of a Novel Target with Intriguing Anti-Tumorigenic Effects in Ovarian Cancer." To identify and test a target that cross-reacts with the CD11b antibody and determines its efficacy in killing both sensitive and chemoresistant ovarian cancer cells.
Source: NIH/NICHD R01, Proposal #17-0220
Date: 09/01/17 – 08/31/22
Total Direct Costs: \$1,919,600

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: "Novel Marker of Survival in Ovarian Cancer Cells." To test the anti-tumorigenic potential of integrin $\alpha V/\beta 1$ antibodies in sensitive and chemoresistant ovarian cancer.
Source: U.S. Department of Defense (DOD)
Date: 01/01/18 – 12/31/19
Total Direct Costs: \$385,000

Role: Principal Investigator, Percent Effort: 25%

Title: "Cross-Talk Between MPO and iNOS Regulates Apoptosis in Chemoresistant Ovarian Cancer." To determine whether chemoresistance in ovarian cancer manifests decreased apoptosis through enhanced s-nitrosylation of caspase-3 mechanism, which can be reversed by DCA.

Source: NIH/NICHD R21

Date: 09/01/17 – 08/31/19

Total Direct Costs: \$423,500

Role: Principal Investigator, Percent Effort: 10%

Title: "A Novel Target with Intriguing Anti-Tumorigenic Effects in Cancer." To identify and test a target that cross-reacts with the CD11b antibody and determines its efficacy in killing both sensitive and chemoresistant ovarian cancer cells.

Source: NIH/DHHS Small Business Technology Transfer Grant (STTR), R41

Date: 07/01/17 – 6/30/18

Total Direct Costs: \$299,999

Role: Principal Investigator, Percent Effort: NA

Title: "A Novel Target with Intriguing Anti-Tumorigenic Effects in Cancer." To identify and test a target that cross-reacts with the CD11b antibody and determines its efficacy in killing both sensitive and chemoresistant ovarian cancer cells.

Source: The Honorable Tina Brozman Foundation, Inc. for Ovarian Cancer Research – Letter of Intent

Date: 2017

Total Direct Costs: \$100,000

Role: Principal Investigator, Percent Effort: 5%; Co-Principal Investigator: NM King, PhD

Title: "Potential Anti-Tumorigenic Antigen for Cancer Therapy." To identify and test a target that cross-reacts with the CD11b antibody and determines its efficacy in killing both sensitive and chemoresistant ovarian cancer cells.

Source: Elsa U. Pardee Foundation Grant Program, Proposal #17-0715

Date: 01/01/18 – 12/31/18

Total Direct Costs: \$187,958

Role: Principal Investigator, Percent Effort: NA

Title: "A Novel Target with Intriguing Anti-Tumorigenic Effects in Cancer." To identify and test a target that cross-reacts with the CD11b antibody and determines its efficacy in killing both sensitive and chemoresistant ovarian cancer cells.

Source: Ovarian Cancer Research Fund Alliance, Inc. (OCRFA)

Date: 01/01/18 – 12/31/20

Total Direct Costs: \$300,000

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD

Title: "Antitumor Effects of Targeting Integrin $\alpha V/\beta 1$ in Ovarian Cancer Cells." To test the anti-tumorigenic potential of integrin $\alpha V/\beta 1$ antibodies in ovarian cancer patient samples.

Source: Ovarian Cancer Research Fund Alliance, Inc., Ann Schreiber Mentored Investigator Award

Date: 01/01/18 – 12/31/18

Total Direct Costs: \$75,000

Pending Other Grants and Contracts

Role: Principal Investigator

Title: "Repurposing ABCIXIMAB, A Clinically Approved Anticoagulant for the Treatment of Ovarian Cancer." To determine whether abciximab is an effective therapy against sensitive and resistant ovarian cancer.

Source: Michigan Ovarian Cancer Alliance (MIOCA)

Date: 04/01/17 – 03/31/18

Total Direct Costs: \$50,000

Role: Principal Investigator

Title: "ReoPro and Ovarian Cancer."

Source: Michigan Ovarian Cancer Alliance (MIOCA)

Date: 04/01/17 – 03/31/18

Total Direct Costs: \$50,000

Role: Principal Investigator

Title: "A Novel Target with Intriguing Anti-Tumorigenic Effects in Cancer."

Source: DS Biotech, LLC, Proposal #17-0289

Date: 07/01/17– 06/30/18

Total Direct Costs: \$100,000

Submitted National/International Grants and Contracts

Role: Principal Investigator

Title: "A Novel Target with Intriguing Anti-Tumorigenic Effects in Ovarian Cancer."

Source: Rivkin Center for Ovarian Cancer, Pilot Study Awards, 573569

Previously Funded Grants and Contracts

Role: Co-Principal Investigator; Principal Investigators: MP Diamond, MD, EN Kraiselburd, PhD

Title: "WSU-UPR Research Partnership to Promote Diversity in the Reproductive Sciences"

Source: NIH/NICHD, HD-09-008

Date: 08/2010 – 07/2015

Total Direct Costs: \$3,020,000

Role: Co-Principal Investigator, Principal Investigator: MP Diamond, MD

Title: "WSU Clinical and Translational Science Award Planning Grant"

Source: NIH/NICHD, 1P20 RR 023578

Date: 09/2006 – 09/2012

Total Direct Costs: \$2,225,750

Role: Consultant; Principal Investigator: MP Diamond, MD

Title: "WSU Cooperative Reproductive Medicine Network Center"

Source: NIH/NICHD, U10 HD-39005

Date: 08/2007 – 07/2012

Total Direct Costs: \$1,510,000

Role: Principal Investigator, Percent Effort: 3.60%

Title: "Postoperative Adhesion: Roles of Hypoxia and Nitric Oxide"

Source: NIH/NICHD, Division of Pharmacology, Physiology, and Biological Chemistry, 1R01
GM069941-01A3

Date: 10/01/06 – 09/30/12

Total Direct Costs: \$1,312,500

Role: Mentor; Principal Investigator: J White, MS, PhD Candidate (WSU)

Title: "Post-Operative Adhesions: Roles of Hypoxia in Nitric Oxide"

Source: NIH/NICHD, Minority Research Supplemental Award, 3R01GM069941-02S1

Date: 01/01/08 – 08/31/10

Total Direct Costs: \$151,441

Role: *Principal Investigator

Title: "*CUAAH Subcontract – Specialty Laboratory Core"

Date: 06/01/08 – 05/31/10

Total Direct Costs: \$403,840

Principal Investigator: JM Flack, MD

Title: "Center for Urban African American Health (CUAAH)"

Source: NIH/NIEHS

Date: 06/01/07 – 05/31/10

Total Direct Costs for Center: \$9,487,709

Role: Principal Investigator

Title: "Angiogenesis of Ovarian Cancer"

Source: Frank Iacobell Endowed Chair, Department of Obstetrics and Gynecology, Wayne State
University School of Medicine

Date: 01/01/08 – 12/31/09

Total Direct Costs: \$41,500

Role: Co-Principal Investigator; Principal Investigator: R Kannan, PhD

Title: "Wayne State University, Department of Engineering – Subcontract"

Source: President's Research Award, Technology and Transfer Office

Date: 01/01/08 – 12/31/09

Total Direct Costs: \$15,000

Role: Consultant; Principal Investigator: MP Diamond, MD U10 HD-39005

Title: "WSU Cooperative Reproductive Medicine Network Center"

Source: NIH/NICHD

Date: 04/01/00 – 03/31/07

Total Direct Costs: \$1,349,994

Role: Principal Investigator; Co-Principal Investigator: MP Diamond, MD

Title: "Testing of Perfluorodecalin for Adhesion Prevention"

Source: Novel Pharma, Inc.

Date: 11/01/01 – 06/30/02

Total Direct Costs: \$32,000

Role: Principal Investigator; Co-Principal Investigator: MP Diamond, MD
Title: "Effect of Tissel on Human Peritoneal Fibroblasts"
Source: Baxter Research Grant
Date: 09/30/01 – 12/31/02
Total Direct Costs: \$98,000

Role: Co-Principal Investigator; Principal Investigator: MP Diamond, MD
Title: "Why Does Endometriosis Cause Adhesions?"
Source: Endometriosis Association
Date: 01/01/01 – 12/31/01
Total Direct Costs: \$38,000

Role: Co-Principal Investigator; Principal Investigator: MP Diamond, MD
Title: "Effect of Tissel on Human Mesothelial Cell Culture"
Source: Baxter Research Grant
Date: 01/01/01 – 08/31/01
Total Direct Costs: \$60,000

Role: Principal Investigator
Title: "The Effects of Hypoxia on the Levels of Peritoneal ECM Proteins"
Source: Wayne State University Department of Obstetrics and Gynecology, Interdepartmental
Research Grant
Date: 03/01/98 – 12/31/00
Total Direct Costs: \$19,000

Role: Principal Investigator
Title: "The Role of p53 in the Pathogenesis of Keloids"
Source: Henry Ford Hospital Small Project Award
Date: 01/01/98 – 12/31/98
Total Direct Costs: \$20,000

Role: Principal Investigator
Title: "Patterns of Cytokine Expression in Cutaneous T-Cell Lymphoma"
Source: Henry Ford Hospital Small Project Award
Date: 01/01/93 – 12/31/94
Total Direct Costs: \$20,000

Previously Submitted, Not Funded Grants and Contracts

Role: Principal Investigator, Percent Effort: 20%
Title: "Novel Mechanisms of Apoptosis in Chemoresistant Ovarian Cancer Cells." To determine whether chemoresistance in ovarian cancer manifests decreased apoptosis through enhanced s-nitrosylation of caspase-3 mechanism, which can be reversed by DCA.

Source: NIH/NICHD, R21
Date: 04/01/17 – 03/31/19
Total Direct Costs: \$423,500

Role: Principal Investigator
Title: “Novel Mechanisms of Apoptosis in Chemoresistant Ovarian Cancer Cells.” To determine whether chemoresistance in ovarian cancer manifests decreased apoptosis through enhanced s-nitrosylation of caspase-3 mechanism, which can be reversed by DCA.
Source: Elsa U. Pardee Foundation Grant Program
Date: 01/01/17 – 12/31/17
Total Direct Costs: \$113,966

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “Novel Mechanisms of Apoptosis in Chemoresistant Ovarian Cancer Cells.” The project’s design is to determine whether chemoresistance in ovarian cancer manifests decreased apoptosis through enhanced s-nitrosylation of caspase-3 mechanism, which can be reversed by DCA.
Source: NIH/NICHD, R03
Date: 12/01/16 – 11/30/18
Total Direct Costs: \$50,000

Role: Principal Investigator
Title: “Innovative New Target for Ovarian Cancer Therapy.” The project was designed to identify and test a target that cross-reacts with the CD11b antibody and determines its efficacy in killing both sensitive and chemoresistant ovarian cancer cells.
Source: The Honorable Tina Brozman Foundation, Inc. for Ovarian Cancer Research
Date: 08/01/16 – 07/31/18
Total Direct Costs: \$200,000

Role: Principal Investigator
Title: “Redox Enzyme-Mediated Prosurvival of Chemoresistance in Ovarian Cancer.” To determine whether development of chemoresistance in ovarian cancer is attributed to enhanced oxidative stress leading to a genotype switch in key oxidant and antioxidant enzymes.
Source: Ovarian Cancer Research Fund Alliance, Inc. (OCRFA)
Date: 2016 – 2019
Total Direct Costs: \$900,000

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “Chemoresistant Ovarian Cancer Cells Manifest Lower Vascular Endothelial Growth Factor and Hypoxia Inducible Factor-1 α : A Potential Survival Mechanism.” The design of the project was to determine whether VEGF and HIF-1 α contribute to the persistence of chemoresistance in ovarian cancer.
Source: Ovarian Cancer Research Fund, Ann Schreiber Mentored Investigator Award
Date: 2016 – 2017
Total Direct Costs: \$75,000

Role: Mentor, Percent Effort: 0%; PI: NM King, PhD
Title: “Novel Biomarkers for Early Detection of Ovarian Cancer.” The design of the project was to determine whether MPO and free iron could be utilized as biomarkers for the early detection of ovarian cancer.
Source: NIH/NICHD, R03 – Resubmission of scored proposal

Date: 12/01/15–11/30/17
Total Direct Costs: \$153,583

Role: Principal Investigator, Percent Effort: 30%
Title: “Redox Enzyme-Mediated Prosurvival of Chemoresistance in Ovarian Cancers.” The design of the project was to determine whether development of chemoresistance in ovarian cancer is attributed to enhanced oxidative stress leading to a genotype switch in key oxidant and antioxidant enzymes.
Source: NIH/NICHD, R01
Date: 12/01/15 – 11/30/20
Total Direct Costs: \$2,494,526

Role: Mentor, Percent Effort: 0%; PI: NM King, PhD
Title: “Novel Biomarkers for Early Detection of Ovarian Cancer.” The design of the project was to determine whether MPO and free iron could be utilized as biomarkers for the early detection of ovarian cancer.
Source: NIH/NICHD, R03
Date: 11/01/14 – 10/31/16
Total Direct Costs: \$152,000

Role: Principal Investigator, Percent Effort: 30%
Title: “Chemoresistance Induces a Genotype Switch in Redox Enzymes in Ovarian Cancer.” The design of the project was to determine whether development of chemoresistance in ovarian cancer is attributed to enhanced oxidative stress leading to a genotype switch in key oxidant and antioxidant enzymes.
Source: NIH/NICHD, R01
Date: 04/01/15 – 03/31/20
Total Direct Costs: \$3,124,495

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “Biomarkers for Early Detection of Ovarian Cancer.” The design of the project was to determine whether MPO and free iron could be utilized as biomarkers for the early detection of ovarian cancer.
Source: Sandy Rollman Ovarian Cancer Foundation (SROCF) Fellowship
Date: 06/01/14 – 05/31/15
Total Direct Costs: \$50,000

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “Novel Biomarkers for Early Detection of Ovarian Cancer.” The design of the project was to determine whether MPO and free iron could be utilized as biomarkers for the early detection of ovarian cancer.
Source: Ladies Auxiliary to the Veterans of Foreign Wars, Postdoctoral Cancer Research Fellowship
Date: 06/01/14 – 05/31/16
Total Direct Costs: \$50,000

Role: Mentor, Percent Effort: 0%; PI: NM King, PhD
Title: “Novel Biomarkers for Early Detection of Ovarian Cancer.” The design of the project was to determine whether MPO and free iron could be utilized as biomarkers for the early detection of ovarian cancer.
Source: Kaleidoscope of Hope Foundation, Young Investigator Award

Date: 04/01/14 – 03/31/15
Total Direct Costs: \$50,000

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “Novel Biomarkers for Early Detection of Ovarian Cancer.” The design of the project was to determine whether MPO and free iron could be utilized as biomarkers for the early detection of ovarian cancer.
Source: Damon Runyon Cancer Research Foundation
Date: 07/01/14 – 06/30/17
Total Direct Costs: \$158,000

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “Chemoresistance Induces a Genotype Switch in Epithelial Ovarian Cancer Cells.” The project was designed to determine whether development of chemoresistance in ovarian is attributed to enhanced oxidative stress leading to a genotype switch in key oxidant and antioxidant enzymes.
Source: American Cancer Society Postdoctoral Fellowship
Date: 01/01/15 – 12/31/18
Total Direct Costs: \$163,500

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “Novel Biomarkers for the Early Detection of Ovarian Cancer.” The design of the project was to determine whether MPO and free iron can be utilized as biomarkers for the early detection of ovarian cancer.
Source: American Association for Cancer Research
Date: 2015 – 2016
Total Direct Costs: \$50,000

Role: Principal Investigator, Percent Effort: 30%
Title: “Postoperative Adhesion Development is Controlled by Mechanisms that Emanate from a Hypoxia-Induced Genotype Switch in Key Enzymes of Oxidative Stress.” Identification of markers that are strongly associated with adhesions and in patients will contribute to both the delineation of mechanisms of adhesion development and serve as potential targets for therapy and intervention.
Source: NIH/NICHD, R01
Date: 07/01/15 – 06/30/20
Total Direct Costs: \$1,921,633

Role: Principal Investigator, Percent Effort: 25%
Title: “Combination of Antioxidants Effectively Reduces Adhesion Development.” The design of the project was to determine the effects of antioxidants on the prevention of postoperative adhesion development.
Source: NIH/NICHD, R03
Date: 07/01/15 – 06/30/17
Total Direct Costs: \$153,314

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “New Insights into the Pathogenesis of Ovarian Cancer.” To identify keymarkers of oxidative stress that have the potential to serve as screening tools for ovarian cancer and may play a role in the acquisition of chemoresistance.
Source: Prevent Cancer Foundation

Date: 04/01/14 – 01/31/16
Total Direct Costs: \$80,000

Role: Mentor, Percent Effort: 0%; Principal Investigator: AO Awonuga, MD
Title: “Effects of Dietary Lycopene on Incidence and Severity of Postoperative Adhesions.” The design of the project was to determine the effects of antioxidants on the prevention of postoperative adhesion development.
Source: NIH/NICHD, R03
Date: 09/01/14 – 08/31/16
Total Direct Costs: \$152,000

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “Novel Biomarkers for Detection of Early Ovarian Cancer.” The design of the project was to determine whether MPO and free iron can be utilized as biomarkers for the early detection of ovarian cancer.
Source: Marsha Rivkin Center for Ovarian Cancer Research, Scientific Scholar Award – Postdoctoral Fellowship
Date: 04/01/14 – 03/31/15
Total Direct Costs: \$60,000

Role: Mentor; Percent Effort: 0%; Principal Investigator: J Belotte, MD
Title: “Catalase SNP as a Genetic Predictor for Epithelial Ovarian Cancer.” The design of the project was to determine whether a SNP in the catalase gene can be utilized as a predictive marker for epithelial ovarian cancer.
Source: Marsha Rivkin Center for Ovarian Cancer Research, Scientific Scholar Award – Postdoctoral Fellowship
Date: 04/01/14 – 03/31/15
Total Direct Costs: \$60,000

Role: Mentor, Percent Effort: 0%; Principal Investigator: NM King, PhD
Title: “Novel Biomarkers for the Early Detection of Ovarian Cancer.” The design of the project was to determine whether MPO and free iron can be utilized as biomarkers for the early detection of ovarian cancer.
Source: Hope Funds Cancer Research Postdoctoral Fellowship
Date: 2014 – 2016
Total Direct Costs: \$100,000

Role: Principal Investigator
Title: “Chemoresistance in Ovarian Cancer Manifests a Genotype Switch in Oxidant Enzymes.” The design of the project was designed to determine whether a genotype switch in key oxidant enzymes is induced in chemotherapy treated ovarian cancer cells and the subsequent effect of the enzymatic activity.
Source: Marsha Rivkin Center for Ovarian Cancer Research; Pilot Study
Date: 04/01/14 – 03/31/15
Total Direct Costs: \$75,000

Role: Principal Investigator, Percent Effort: 30%; Co-Investigators: MP Diamond, MD, S Ghamande, PhD
Title: “Chemoresistance Induces a Genotype Switch in Redox Enzymes in Ovarian Cancer.” The design of the project was to determine whether development of chemoresistance in ovarian

cancer were attributed to enhanced oxidative stress leading to a genotype switch in key oxidant and antioxidant enzymes.

Source: NIH/NICHD, R01

Date: 07/01/14 – 06/30/19

Total Direct Costs: \$2,932,687

Role: Principal Investigator, Percent Effort: 25%

Title: "Chemoresistance in Ovarian Cancer is Attributed to Enhanced Oxidative Stress." The design of the project was to determine whether development of chemoresistance in ovarian cancer were attributed to enhanced oxidative stress.

Source: NIH/NICHD, R03

Date: 07/01/14 – 06/30/16

Total Direct Costs: \$152,000

Role: Principal Investigator, Percent Effort: 25%

Title: "Chemoresistance in Ovarian Cancer Manifests a Genotype Switch in Oxidant Enzymes." The design of the project was to determine whether development of chemoresistance in ovarian cancer were attributed to enhanced oxidative stress leading to a genotype switch in key oxidant and antioxidant enzymes.

Source: NIH/NICHD, R03

Date: 07/01/14 – 06/30/16

Total Direct Costs: \$152,000

Role: Mentor, Percent Effort: 0%; Principal Investigator: J Belotte, MD

Title: "Characterization of Epithelial Ovarian Cancer Stem Cells." The design of the project was to determine the role of pluripotency markers in epithelial ovarian cancer and the association with survival.

Source: NIH/NICHD, R03

Date: 09/30/14 – 06/30/16

Total Direct Costs: \$152,000

Role: Mentor, Percent Effort: 0%; PI: J Belotte, MD

Title: "Catalase SNP as a Genetic Predictor for Epithelial Ovarian Cancer." The design of the project was to determine whether a SNP in the catalase gene can be utilized as a predictive marker for epithelial ovarian cancer.

Source: NIH/NICHD, R03

Date: 09/30/14 – 08/31/16

Total Direct Costs: \$152,000

Role: Principal Investigator, Percent Effort: 20%

Title: "Innovative New Target for Ovarian Cancer Therapy." The project was designed to identify and test a target that cross-reacts with the CD11b antibody and determines its efficacy in killing both sensitive and chemoresistant ovarian cancer cells.

Source: NIH/NICHD, R21

Date: 12/31/16 – 11/30/18

Total Direct Costs: \$275,000

Role: Principal Investigator

Title: "Redox Enzyme-Mediated Prosurvival of Chemoresistance in Ovarian Cancer." The design of the project was to determine whether development of chemoresistance in ovarian

cancer were attributed to enhanced oxidative stress leading to a genotype switch in key oxidant and antioxidant enzymes.

Source: Ovarian Cancer Research Fund, Program Project Development Grant

Date: 2016 – 2019

Total Direct Costs: \$900,000

Role: Principal Investigator, Percent Effort: 20%

Title: “Novel Mechanisms of Apoptosis in Chemoresistant Ovarian Cancer Cells.” The design of the project was to determine whether chemoresistance in ovarian cancer manifests decreased apoptosis through enhanced s-nitrosylation of caspase-3 mechanism, which can be reversed by DCA.

Source: NIH/NICHD, R21

Date: 12/01/16 – 11/30/18

Total Direct Costs: \$275,000

Role: Mentor, Percent Effort 0%; Principal Investigator: NM King, PhD

Title: “Novel Biomarkers for Early Detection of Ovarian Cancer.” The design of the project was to determine whether MPO and free iron can be utilized as biomarkers for the early detection of ovarian cancer.

Source: L’Oreal USA for Women in Science Fellowship

Date: 2016 – 2017

Total Direct Costs: \$60,000

PATENTS:

Status: Provisional Submission

Date: 2016

Number: WSU

Title: Compositions and Methods Targeting CD11b/CD18, Myeloperoxidase and/or Integrin Alpha and Beta 1 to Treat Solid Tumors

Role: Inventor

Status: Pending

Date: 2015

Number: WSU

Title: Novel Approach to Selectively Kill Cancer Cells

Role: Inventor

Status: Pending

Date: 2008

Number: WSU

Title: Anticancer Vaccine

Role: Inventor

Status: Pending
Date: WSU
Number: WSU 00-492
Title: Prevention of Adhesions
Role: Inventor

Status: Pending
Date: March 18, 2004
Number: WSU
Title: Regulation of Peritoneal Healing and Adhesion Development
Role: Inventor

Status: Pending
Date: June 25, 2002
Number: WSU
Title: Modification of Healing and Adhesion Development
Role: Inventor

PUBLICATIONS

Peer-Reviewed Publications

**Indicates student, trainee, or postdoctoral*

Reports of Original Work

1. **Saed GM**, *Fletcher NM, Diamond MP, Morris RT, Gomez-Lopez N, *Memaj I. Novel expression of CD11b in epithelial ovarian cancer: potential therapeutic target. *Gynecologic Oncology* 2018 Mar;148(3):567-575. [Epub 2018 Jan 10] PMID: 29329880. *Role: Writer and Mentor*
2. Detti L, *Fletcher NM, **Saed GM**, Peregrin-Alvarez I, Uhlmann RA. Anti-Müllerian Hormone (AMH) may stall ovarian cortex function through modulation of hormone receptors other than the AMH receptor. *Reproductive Sciences* January 1:19337119117737850, 2017. [Epub ahead of print] PMID: 29141508. *Role: Mentor and collaborator*
3. *Fletcher NM, *Abusamaan MS, *Memaj I, *Saed MG, Al-Hendy A, Diamond MP, **Saed GM**. Oxidative stress: a key regulator of leiomyoma cell survival. *Fertility and Sterility* 107(6):1387-1394.e1, 2017. Epub May 5, 2017. PMID: 28483502. *Role: Writer and Mentor*
4. **Saed GM**, Diamond MP, Fletcher NM. Updates of the role of oxidative stress in the pathogenesis of ovarian cancer. *Gynecologic Oncology* 2017 Jun;145(3):595-602. Epub 2017 Feb 23. Review. PMID:28237618. *Role: Writer and Mentor*
5. *Fletcher NM, *Belotte J, *Saed MG, *Memaj I, Diamond MP, Morris RT, **Saed GM**. Specific point mutations in key redox enzymes are associated with chemoresistance in epithelial ovarian cancer. *Free Radical Biology and Medicine* 102:122-132, 2017. Epub November 25, 2016. PMID: 27890641. *Role: Mentor and Writer*

6. *Nusrat O, *Belotte J, *Fletcher NM, *Memaj I, *Saed MG, Diamond MP, **Saed GM**. The role of angiogenesis in the persistence of chemoresistance in epithelial ovarian cancer. *Reproductive Sciences* 23(11):1484-1492, 2016. Epub April 26, 2016. PMID: 27122375
Role: Mentor and Writer
7. *Shaeib F, *Khan SN, *Thakur M, Kohan-Ghadr HR, Drewlo S, **Saed GM**, Pennathur S, Abu-Soud HM. The impact of myeloperoxidase and activated macrophages on metaphase II mouse oocyte quality. *PLoS One* 11(3):e0151160, 2016. eCollection 2016. PMID: 26982351
Role: Mentor and collaborator
8. Ahmed RS, Liu G, Renzetti A, Farshi P, Yang H, Soave C, **Saed G**, El-Ghoneimy AA, El-Banna HA, Foldes R, Chan TH, Dou QP. Biological and Mechanistic Characterization of Novel Prodrugs of Green Tea Polyphenol Epigallocatechin Gallate Analogs in Human Leiomyoma Cell Lines. *J Cell Biochem.* 2016 Oct;117(10):2357-69.doi: 10.1002/jcb.25533. Epub 2016 Mar 28. PMID:26950525. *Role: Collaborator*
9. *Fletcher NM, Awonuga AO, *Abusamaan MS, *Saed MG, Diamond MP, **Saed GM**. Adhesion phenotype manifests an altered metabolic profile favoring glycolysis. *Fertility and Sterility* 105(6):1628-1637, 2016. Epub February 23, 2016. PMID: 26920255. *Role: Mentor and Writer.*
10. **Saed GM**, *Fletcher NM, Diamond MP. The creation of a model for ex vivo development of postoperative adhesions. *Reproductive Sciences* 23(5):610-622, 2016. Epub September 25, 2015. PMID: 26408397. *Role: Mentor.*
11. *Belotte J, *Fletcher NM, *Saed MG, *Abusamaan MS, *Dyson G, Diamond MP, **Saed GM**. A single nucleotide polymorphism in catalase is strongly associated with ovarian cancer survival. *PLoS One* 10(8):e0135739, 2015. eCollection 2015. PMID: 26301412 PMCID: PMC4547699. *Role: Mentor and Writer*
12. *Fletcher NM, Awonuga AO, *Neubauer BR, *Abusamaan MS, *Saed MG, Diamond MP, **Saed GM**. Shifting anaerobic to aerobic metabolism stimulates apoptosis through modulation of redox balance: potential intervention in the pathogenesis of postoperative adhesions. *Fertility and Sterility* 104(4):1022-1029, 2015. Epub July 26, 2015. PMID: 26215756. *Role: Mentor and Writer*
13. *Khan SN, *Shaeib F, *Najafi T, *Kavdia M, Gonik B, **Saed GM**, Goud PT, Abu-Soud HM. Diffused intra-oocyte hydrogen peroxide activates myeloperoxidase and deteriorates oocyte quality. *PLoS One* 10(7):e0132388, 2015. eCollection 2015. PMID: 26197395 PMCID: PMC4511228 *Role: Mentor, collaborator, assisted with experimental format*
14. *Fortin CN, **Saed GM**, Diamond MP. Predisposing factors to post-operative adhesion development. *Hum Reprod Update.* 2015 Jul-Aug;21(4):536-51.doi: 10.1093/humupd/dmv021. Epub 2015 May 1. Review. PMID:25935859. *Role: Mentor and Writer*

15. *Shaeib F, *Khan SN, *Ali I, *Najafi T, *Maitra D, *Abdulhamid I, **Saed GM**, Pennathur S, Abu-Soud HM. Melatonin prevents myeloperoxidase heme destruction and the generation of free iron mediated by self-generated hypochlorous acid. PLoS One 10(3):e0120737, 2015. eCollection 2015. PMID: 25835505 PMCID: PMC4383586 *Role: Mentor, collaborator, assisted with writing of article*
16. *Maitra D, *Ali I, *Abdulridha RM, *Shaeib F, *Khan SN, **Saed GM**, Pennathur S, Abu-Soud HM. Kinetic studies on the reaction between dicyanocobinamide and hypochlorous acid. PLoS One 9(11):e110595, 2014. PMID: 25375773. PMCID: PMC4222763. *Role: Mentor, collaborator, assisted with manuscript writing*
17. Abu-Soud HM, *Maitra D, *Shaeib F, *Khan SN, *Byun J, *Abdulhamid I, *Yang Z, **Saed GM**, Diamond MP, Andreana PR, Pennathur S. Disruption of heme-peptide covalent cross-linking in mammalian peroxidases by hypochlorous acid. Journal of Inorganic Biochemistry 140:245-254, 2014. Epub July 8, 2014. PMID: 25193127 PMCID: PMC4449957. *Role: Mentor and collaborator.*
18. *Belotte J, *Fletcher NM, *Alexis M, Morris RT, Munkarah AR, Diamond MP, **Saed GM**. Sox2 gene amplification significantly impacts overall survival in serous epithelial ovarian cancer. Reproductive Sciences 22(1):38-46, 2015. Epub July 18, 2014. PMID: 25038052. PMCID: PMC4275450. *Role: Mentor and Writer*
19. Goud PT, Goud AP, *Najafi T, Gonik B, Diamond MP, **Saed GM**, Zhang X, Abu-Soud HM. Direct real-time measurement of intra-oocyte nitric oxide concentration in vivo. PLoS One 9(6):e98720, 2014. PMID: 24887331 PMCID: PMC4041775 *Role: Collaborator and assisted with manuscript writing.*
20. *Awonuga AO, *Belotte J, *Abuanzeh S, *Fletcher NM, Diamond MP, **Saed GM**. Advances in the Pathogenesis of Adhesion Development: The Role of Oxidative Stress. Reprod Sci. 2014 Jul;21(7):823-836. Epub 2014 Feb 11. Review. PMID:24520085. *Role: Mentor and Writer.*
21. *Fletcher NM, *Saed MG, *Abuanzeh S, Abu-Soud HM, Al-Hendy A, Diamond MP, **Saed GM**. Nicotinamide adenine dinucleotide phosphate oxidase is differentially regulated in normal myometrium versus leiomyoma. Reproductive Sciences 21(9):1145-1152, 2014. Epub February 11, 2014. PMID: 24520084 *Role: Mentor and Writer.*
22. *Fletcher NM, *Abuanzeh S, *Saed MG, Diamond MP, Abu-Soud HM, **Saed GM**. Nicotinamide adenine dinucleotide phosphate oxidase expression is differently regulated to favor a pro-oxidant state that contributes to postoperative adhesion development. Reproductive Sciences 21(8):1050-1059, 2014. Epub February 10, 2014. PMID: 24516041. *Role: Mentor and Writer*
23. *Detti L, *Uhlmann RA, *Zhang J, Diamond MP, **Saed GM**, *Fletcher NM, Lu M, Williams LJ. Goserelin fosters bone elongation, but does not prevent ovarian damage in cyclophosphamide-treated prepubertal mice. Fertility and Sterility 101(4):1157-1164.e.1, 2014. Epub January 23, 2014. PMID: 24462062. *Role: Collaborator and mentor*

24. *Fletcher NM, Awonuga AO, *Saed MG, Abu-Soud HM, Diamond MP, **Saed GM**. Lycopene, a powerful antioxidant, significantly reduces the development of the adhesion phenotype. *Systems Biology in Reproductive Medicine* 60(1):14-20, 2014. Epub November 12, 2013. PMID: 24219141. *Role: Mentor and Writer*
25. *[†]Belotte J, *[†]Fletcher NM, Awonuga AO, *Alexis M, Abu-Soud HM, Saed MG, Diamond MP, **Saed GM**. The role of oxidative stress in the development of Cisplatin resistance in epithelial ovarian cancer. [†]Denotes co-authorship. *Reproductive Sciences* 21(4):503-508, 2014. Epub September 27, 2013. PMID: 24077440 PMCID: PMC3960837
26. Detti L,* Uhlmann RA, Lu M, Diamond MP, **Saed GM**, *Fletcher NM, Zhang J, Williams LJ. Serum markers of ovarian reserve and ovarian histology in adult mice treated with cyclophosphamide in pre-pubertal age. *Journal of Assisted Reproduction and Genetics* 30(11):1421-1429, 2013. Epub September 24, 2013. PMID: 24057193, PMCID: PMC3879939. *Role: Collaborator and mentor, assisted with experimental design.*
27. Detti L, Uhlmann RA, *Fletcher NM, Diamond MP, **Saed GM**. Endometrial signaling pathways during ovarian stimulation for assisted reproduction technology. *Fertility and Sterility* 100(3): 889-894, 2013. Epub June 24, 2013. PMID: 23806847 PMCID: PMC3880797.
28. *Banerjee J, *Shaeib F, *Maitra D, **Saed GM**, Dai J, Diamond MP, Abu-Soud HM. Peroxynitrite affects the cumulus cell defense of metaphase II mouse oocytes leading to disruption of the spindle structure in vitro. *Fertility and Sterility* 100(2):578-584.e1, 2013. Epub May 28, 2013. PMID: 23721714. *Role: Mentor and collaborator*
29. *Maitra D, *Shaeib F, *Abdulhamid I, *Abdulridha RM, **Saed GM**, Diamond MP, Pennathur S, Abu-Soud HM. Myeloperoxidase acts as a source of free iron during steady-state catalysis by a feedback inhibitory pathway. *Free Radical and Biological Medicine* 63:90-98, 2013. Epub April 25, 2013. PMID: 23624305 PMCID:PMC3863623. *Role: Mentor and collaborator*
30. *Ambler DR, *Fletcher NM, Diamond MP, Saed GM. Effects of hypoxia on the expression of inflammatory markers IL-6 and TNF- α in human normal peritoneal and adhesion fibroblasts. *Systems Biology and Reproductive Medicine* 58(6):324-329, 2012. Epub October 8, 2012. PMID: 2304632
31. *Maitra D, *Abdeulhamid I, Diamond MP, **Saed GM**, Abu-Soud HM. Melatonin attenuates hypochlorous acid-mediated heme destruction, free iron release, and protein aggregation in hemoglobin. *Journal of Pineal Research* 53(2):198-205, 2012. Epub March 30, 2012. PMID: 22462755. *Role: Mentor and collaborator*
32. *Ambler DR, *Golden AM, *Gell JS, **Saed GM**, Carey DJ, Diamond MP. Microarray expression profiling in adhesion and normal peritoneal tissues. *Fertility and Sterility* 97(5):1158-1164.e1-4, 2012. Epub February 22, 2012. PMID: 22365381. *Role: Mentor, collaborator, assisted with writing of article*
33. *Shavell VI,*Fletcher NM, *Jiang ZL, **Saed GM**, Diamond MP .Uncoupling oxidative phosphorylation with 2,4-dinitrophenol promotes development of the adhesion phenotype. *Fertility and Sterility* 97(3):729-733, 2012. Epub December 24, 2011. PMID: 22200174. *Role: Mentor and Writer.*

34. Abu-Soud HM, *Maitra D, *Byun J, *Souza CE, *Banerjee J, Saed GM, Diamond MP, Andreana PR, Pennathur S. The reaction of HOCl and cyanocobalamin: corrin destruction and the liberation of cyanogen chloride. *Free Radical and Biological Medicine* 52(3):616-625, 2012. Epub November 10, 2011. PMID: 22138102 PMCID:PMC3786219. Role: Mentor and collaborator.
35. *Souza CE, *Maitra D, **Saed GM**, Diamond MP, Moura AA, Pennathur S, Abu-Soud HM. Hypochlorous acid-induced heme degradation from lactoperoxidase as a novel mechanism of free iron release and tissue injury in inflammatory diseases. *PLoS One* 6(11):e27641, 2011. Epub November 22, 2011. PMID: 22132121 PMCID:PMC3222650. Role: *Mentor and collaborator*
36. *White JC, *Jiang ZL, Diamond MP, **Saed GM**. Macrophages induce the adhesion phenotype in normal peritoneal fibroblasts. *Fertility and Sterility* 96(3):758-763.e3, 2011. Epub July 27, 2011. PMID: 21794857. Role: *Writer and Mentor*
37. Awonuga AO, Fletcher NM, **Saed GM**., Diamond MP. Postoperative adhesion development following cesarean and open intra-abdominal gynecological operations: a review. *18(12): 1166-85*. Epub July 20, 2011. PMID: 21775773.
38. **Saed GM**, *Fletcher NM, **Jiang ZL, Abu-Soud HM, Diamond MP. Dichloroacetate induces apoptosis of epithelial ovarian cancer cells through a mechanism involving modulation of oxidative stress. *Reproductive Sciences* 18(12):1253-1261, 2011. Epub June 23, 2011. PMID: 21701041. Role: *Writer and Mentor*
39. *Jiang Z, *Fletcher NM, *Ali-Fehmi R, Diamond MP, Abu-Soud HM, Munkarah AR, **Saed GM**. Modulation of redox signaling promotes apoptosis in epithelial ovarian cancer cells. *Gynecologic Oncology* 122(2):418-423, 2011. Epub May 26, 2011. PMID: 21620448 PMCID: PMC4237166. Role: *Writer and Mentor*
40. *Meng Q, *Sun W, *Jiang J, *Fletcher NM, Diamond MP, **Saed GM**. Identification of common mechanisms between endometriosis and ovarian cancer. *Journal of Assisted Reproduction and Genetics* 28(10):917-923, 2011. Epub May 26, 2011. PMID: 21614520 PMCID: PMC3220443. Role: *Writer and Mentor*
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Review Articles

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Non Peer-Reviewed Publications

Other (On-Line Publications) * Indicates student, trainee, or postdoctoral

1. *Nusrat O, *Belotte J, *Fletcher NM, *Memaj I, *Saed MG, Diamond MP, **Saed GM**. The role of angiogenesis in the persistence of chemoresistance in epithelial ovarian cancer. www.OncToday.com, Beyond the Abstract, June 21, 2016.
2. *Belotte J, *Fletcher NM, *Alexis M, Morris RT, Munkarah AR, Diamond MP, **Saed GM**. Sox2 gene amplification significantly impacts overall survival in serous epithelial ovarian cancer. Global Medical Discovery Series (*Key Scientific Article Contributing to Excellence in Biomedical Research*), summer issue 2015.
3. *Fletcher NM, *Saed MG, Abu-Soud HM, Al-Hendy A, Diamond MP, **Saed GM**. Uterine fibroids are characterized by an impaired antioxidant cellular system: potential role of hypoxia in the pathophysiology of uterine fibroids. Featured article. MDLinx.com/obstetrics-gynecology/news-article, November 2013.

PRESENTATIONS

Podium Presentations (Referred)

1. *Novel Target for Ovarian Cancer Immunotherapy*. 48th Annual Meeting of the Society of Gynecologic Oncology's Women's Cancer, National Harbor, MD, March 2017.
2. *Targeting Integrin $\alpha V/\beta 1$ Receptor Manifests Intriguing Anti-Tumor Effects in Sensitive and Chemoresistant Ovarian Cancer Cells: Potential Therapeutic Target*. 64th Annual Scientific Meeting of the Society for Reproductive Investigation, Orlando, FL, March 2017.
3. *Human Adhesion Fibroblasts are Characterized by Reduction in the level of Pluripotency Markers as Compared to Normal Peritoneal Fibroblasts*. 72nd Annual Meeting of the American Society for Reproductive Medicine, Salt Lake City, UT, October 2016.
4. *Anti-Mullerian Hormone (AMH) for Prevention of Tissue Activation after Vitrified/Thawed Ovarian Cortex Xenotransplantation*. 72nd Annual Meeting of the American Society for Reproductive Medicine, Salt Lake City, UT, October 2016.
5. *Dichloroacetate Induces Apoptosis of Uterine Leiomyoma Cells Through A Mechanism Involving Modulation of Oxidative Stress*. 63rd Annual Meeting of the Society for Reproductive Investigation, Montreal, Quebec, Canada, March 2016.
6. *Chemoresistance in Epithelial Ovarian Cancer Cells is Controlled by Mechanisms Emanating from Chemotherapy-Induced Genotype Switch in Glutathione Peroxidase, Through the Up-Regulation of Cytidine Deaminase*. 62nd Annual Meeting of the Society for Reproductive Investigation, San Francisco, CA, March 2015.

7. *Elevated Serum Anti-Müllerian Hormone (AMH) Stalls Ovarian Follicle Development by Downregulating FSH- and LH-Receptors and Inhibin-B Production.* Proceedings of the 71st Annual Meeting of the American Society for Reproductive Medicine, Baltimore, MD, October 2015.
8. *Hypochlorous Acid Reversibly Inhibits Caspase-3: A Potential Regulator of Apoptosis.* Joint Meeting of the 22nd Society for Redox Biology and Medicine (SFRBM) and 17th Society for Free Radical Research International (SFRR), Boston, MA, November 2015.
9. *The In-Vivo Effects of Superoxide Dismutase on the Incidence and Severity of Post-Operative Adhesion Development.* 70th Annual Meeting of the American Society for Reproductive Medicine, Honolulu, HI, October 2014.
10. *Superoxide Dismutase Significantly Delayed the Development of Cisplatin Resistance in Epithelial Ovarian Cancer Cells.* American Association for Cancer Research's Precision Medicine Series: Drug Sensitivity and Resistance. Improving Cancer Therapy Special Conference, Orlando, FL, June 2014.
11. *Chemoresistant Ovarian Cancer Cells Manifest Lower Vascular Endothelial Growth Factor and Hypoxia Induced Factor-1 α : A Potential Survival Mechanism.* American Association for Cancer Research's Precision Medicine Series: Drug Sensitivity and Resistance. Improving Cancer Therapy Special Conference, Orlando, FL, June 2014.
12. *Dichloroacetate Increases Sensitivity to Chemotherapy by Modulation of Antioxidants in Epithelial Ovarian Cancer.* 61st Annual Meeting of the Society for Gynecologic Investigation, Florence, Italy, March 2014.
13. *Catalase and NADPH Oxidase Single Nucleotide Polymorphisms Are Associated with Increased Risk and Serve As Potential Targets for Breast and Ovarian Cancers.* 104th Annual Meeting of the American Association for Cancer Research, Washington, DC, April 2013.
14. *The Role of Oxidative Stress in the Development of Cisplatin Resistance in Epithelial Ovarian Cancer.* Poster session B. Advances in Ovarian Cancer Research: From Concept to Clinic. American Association for Cancer Research, Miami, FL, September 2013.
15. *Catalase and NADPH Oxidase Single Nucleotide Polymorphisms Are Associated with Increased Risk and Serve As Potential Targets for Breast and Ovarian Cancers.* 104th Annual Meeting of the American Association for Cancer Research, Washington, DC, April 2013.
16. *Endometrial Insulin Pathway during Ovarian Stimulation for Assisted Reproductive Technology (ART).* 68th Annual Meeting of the American Society for Reproductive Medicine, San Diego, CA, October 2012.
17. *NADPH Oxidase p22-Phox Gene Polymorphism in Women is Associated with the Development of Postoperative Adhesions.* 59th Annual Meeting of the Society for Gynecologic Investigation, San Diego, CA, March 2012.

18. *Metabolism and Oxidative Stress: Integral Role in Regulation of the Adhesion Phenotype.* 58th Annual Meeting of the Society for Gynecologic Investigation, Miami Beach, FL, March 2011.
19. *Mass Spectrometric Identification of HOCl-Mediated Heme Degradation Products of Hemoglobin.* 59th ASMS Conference on Mass Spectrometry, Denver, CO, 2011.
20. *Inhibition of NADPH Oxidative Reductase Promotes Apoptosis in Epithelial Ovarian Cancer Cells.* 39th Annual Meeting of the Global Congress of Minimally Invasive Gynecology AAGL, Las Vegas, NV, November 2010.
21. *Reaction of Hemoglobin and Red Blood Cells with Hypochlorous Acid and Mechanism of Heme Destruction and Free Iron Release.* 17th Annual Meeting of the Society for Free Radical Biology and Medicine, Orlando, FL, November 2010.
22. *Liquid Chromatography Atmospheric Pressure Ionization Tandem: Mass Spectrometry Identifies Novel Hypochlorous Acid Reaction Products of Lycopene.* 58th Annual Meeting of the American Society of Mass Spectrometry, Salt Lake City, UT, May 2010.
23. *Role of Polychlorinated Biphenyls Enhancement of Lipid Peroxidation in Human Normal Peritoneal and Adhesion Fibroblasts.* 38th Annual Meeting of Global Congress of Minimally Invasive Gynecology AAGL, Orlando, FL, November 2009.
24. *Hydrogen Peroxide Bioavailability Determines the Sensitivity of Human Normal Peritoneal and Adhesion Fibroblasts to Hypoxia-Induced Lipid Peroxidation.* 38th Annual Meeting of Global Congress of Minimally Invasive Gynecology AAGL, Orlando, FL, November 2009.
25. *S-Nitrosylation of Caspase-3 Is the Mechanism by Which Adhesion Fibroblasts Manifest Lower Apoptosis.* 36th Annual Meeting of the American Association of Gynecologic Laparoscopists, Global Congress of Minimally Invasive Gynecology, Washington, DC, November 2007.
26. *Generation of Superoxide by Inducible Nitric Oxide Synthase in L-Arginine Deficient Fibroblasts Established From Human Adhesion Tissues.* 36th AAGL Annual Meeting, Global Congress of Minimally Invasive Gynecology, Washington, DC, November 2007.
27. *Hypoxia Stimulation of Expression of Type I Collagen and Fibronectin in Human Peritoneal and Adhesion Fibroblasts: Blockage by Interferon Gamma.* 36th AAGL Annual Meeting, Global Congress of Minimally Invasive Gynecology, Washington, DC, November 2007.
28. *Superoxide Induces the Adhesion Phenotype: Role of Hypoxia in the Pathogenesis of the Adhesion Development.* Global Congress of Minimally Invasive Gynecology, 36th Annual Meeting of the American Association of Gynecologic Laparoscopists, Washington, DC, November 2007.
29. *Nitric Oxide Synthase Isoforms are Differentially Expressed in Fibroblasts Isolated from Human Normal Peritoneum and Adhesion Tissues.* 63rd Annual Meeting of the American Society for Reproductive Medicine, Washington, DC, October 2007.

30. *Regulation of the Expression of INOS, COX-2, and VEGF in Postoperative Adhesions.* 62nd Annual Meeting of the American Society for Reproductive Medicine, New Orleans, LA, October 2006.
31. *Omega-3 Fatty Acid Prevents and Mitigates the Adhesion Phenotype in Normal Human Peritoneal and Adhesion Fibroblasts.* 62nd Annual Meeting of the American Society for Reproductive Medicine, New Orleans, LA, October 2006.
32. *IL6 Expression in Human Normal Peritoneal and Adhesion Fibroblasts: Regulation by Hypoxia.* 62nd Annual Meeting of the American Society for Reproductive Medicine, New Orleans, LA, October 2006.
33. *The Cross-Talk between Myeloperoxidase and Inducible Nitric Oxide Synthase in Post-operative Adhesions.* 62nd Annual Meeting of the American Society for Reproductive Medicine, New Orleans, LA, October 2006.
34. *TNF-Alpha Expression in Human Normal Peritoneal and Adhesion Fibroblasts: Regulation by Hypoxia.* 62nd Annual Meeting of the American Society for Reproductive Medicine, New Orleans, LA, October 2006.
35. *L-Arginine Deficiency in Fibroblasts Established from Human Adhesion Tissues Leads to the Generation of Superoxide by Inducible Nitric Oxide Synthase.* 53rd Annual Meeting of the Society for Gynecologic Investigation, Toronto, Ontario, Canada, March 2006.
36. *Regulation of Inducible Nitric Oxide Synthase in Post-Operative Adhesions.* 34th Annual Meeting of the American Association of Gynecologic Laparoscopists, Chicago, IL, November 2005.
37. *Cyclooxygenase-2 Inhibitors Enhance Apoptosis of Adhesion Fibroblasts.* 34th Annual Meeting of the American Association of Gynecologic Laparoscopists, Chicago, IL, November 2005.
38. *The Effects of Estradiol on the Expression of Estrogen, Progesterone, Androgen, and Prolactin Receptors in Human Peritoneal Fibroblasts.* 61st Annual Meeting of the American Society for Reproductive Medicine and the 1st Annual Meeting of the Canadian Fertility and Andrology Society, Palais des Congres, Montreal, Quebec, Canada, October 2005.
39. *Possible Role of Natural Immune Response against Fibroblasts in the Development of Post-Operative Adhesions.* 61st Annual Meeting of the American Society for Reproductive Medicine and the 51st Annual Meeting of the Canadian Fertility and Andrology Society, Palais des Congres, Montreal, Quebec, Canada, October 2005.
40. *Knockout of Inducible Nitric Oxide Expression Significantly Reduces the Expression of Type I Collagen and Transforming Growth Factor- β 1 in Human Peritoneal and Adhesion Fibroblasts.* 61st Annual Meeting of the American Society for Reproductive Medicine and the 51st Annual Meeting of the Canadian Fertility and Andrology Society, Palais des Congres, Montreal, Quebec, Canada, October 2005. **Prize Paper Candidate**

41. *Regulation of Inducible Nitric Oxide Synthase in Post-Operative Adhesions.* 52nd Annual Meeting of the Society for Gynecologic Investigation, Los Angeles, CA, March 2005.
42. *Differential Expression of Myeloperoxidase (MPO) in Fibroblasts Isolated from Normal Peritoneal and Adhesion Tissues.* 4th International Peroxidase Meeting Joint with the 10th Myeloperoxidase Meeting, Shimokyo-Ku, Kyoto City, Japan, October 2004.
43. *Fibroblasts Isolated from Normal Peritoneal and Adhesion Tissues Differentially Express Myeloperoxidase (MPO).* 60th Annual Meeting of the American Society for Reproductive Medicine, Philadelphia, PA, October 2004.
44. *Hypoxia Up-Regulates Cyclooxygenase-2 and Prostaglandin E₂ Levels in Human Peritoneal Fibroblasts.* 60th Annual Meeting of the American Society for Reproductive Medicine, Philadelphia, PA, October 2004.
45. *Dichloroacetate Inhibition of Angiogenesis Caused by Hypoxia Treatment of Normal Peritoneal and Adhesion Fibroblasts in Human Umbilical Vein Endothelial Cells.* 60th Annual Meeting of the American Society for Reproductive Medicine, Philadelphia, PA, October 2004.
46. *Dichloroacetate Significantly Increase the Expression of the Transcription Nuclear Factor Kappa- β in Fibroblasts of Human Adhesion Tissues.* 51st Annual Scientific Meeting of the Society for Gynecologic Investigation, Houston, TX, March 2004.
47. *Stimulation of Expression of Vascular Endothelial Growth Factor by Hypoxia from Fibroblasts Isolated from Normal Peritoneum and Adhesion Tissues.* 32nd Annual Meeting of The American Association of Gynecologic Laparoscopists, Las Vegas, NV, November 2003.
48. *Inhibition of Nitric Oxide Production by N-Nitro-L-Arginine Methyl Ester Increased the Expression of Type I Collagen in Human Peritoneal Fibroblasts.* 59th Annual Meeting of American Society for Reproductive Medicine, San Antonio, TX, October 2003.
49. *Apoptosis of Human Peritoneal and Adhesion Fibroblasts After Hypoxia: Role of Inducible Nitric Oxide Synthase.* 59th Annual Meeting of American Society for Reproductive Medicine, San Antonio, TX, October 2003.
50. *Inhibition of Cyclooxygenase-2 in Fibroblasts Isolated from Normal Peritoneum and Adhesion Tissues Decreases the Expression of Hypoxia Inducible Factor-1 Alpha.* 50th Annual Scientific Meeting of the Society for Gynecologic Investigation, Washington, DC, March 2003.
51. *Tissue Plasminogen Activator/Plasminogen Activator Inhibitor-1 (tPA/PAI-1) Modulation by Tisseel.* 50th Annual Scientific Meeting of the Society for Gynecologic Investigation, Washington, DC, March 2003.
52. *Hypoxia Increases the Expression of Vascular Endothelial Growth Factor in Fibroblasts Isolated From Human Normal Peritoneum and Adhesion Tissues.* 50th Annual Scientific Meeting of the Society for Gynecologic Investigation, Washington, DC, March 2003.

53. *Dichloroacetate Significantly Reduces the Expression of Vascular Endothelial Growth Factor in Fibroblasts of Human Adhesion Tissues.* 50th Annual Scientific Meeting of the Society for Gynecologic Investigation, Washington, DC, March 2003.
54. *Transforming Growth Factor-Beta 1 (TGF- β 1) and Extracellular Matrix Production by Human Peritoneal Mesothelial Cells: Effect of Tisseel[®] Fibrin Sealant).* 50th Annual Scientific Meeting of the Society for Gynecologic Investigation, Washington, DC, March 2003.
55. *Cyclooxygenase-2 Inhibition Decreases the Expression of Vascular Endothelial Growth Factor from Fibroblasts Isolated from Normal Peritoneum and Adhesion Tissues.* 50th Annual Scientific Meeting of the Society for Gynecologic Investigation, Washington, DC, March 2003.
56. *Elevation of Type I Collagen mRNA in Peritoneal Adhesions.* 31st Annual Meeting of the American Association of Gynecologic Laparoscopists, Miami, FL, November 2002.
57. *Cyclooxygenase-2 Expression in Human Fibroblasts Isolated from Adhesions But Not from Normal Peritoneal Tissues.* 31st Annual Meeting of the American Association of Gynecologic Laparoscopists, Miami, FL, November 2002.
58. *Existence of p53 Expression in Human Fibroblasts Isolated from Adhesions, But Not from Normal Peritoneal Tissues.* 31st Annual Meeting of the American Association of Gynecologic Laparoscopists, Miami, FL, November 2002.
59. *Matrix Metalloproteinase (MMP-1, MMP-2), and Tissue Inhibitor for Metalloproteinase (TIMP-1) Expression by Human Peritoneal Mesothelial Cells: Effect of Fibrin Sealant.* 58th Annual Meeting of the American Society for Reproductive Medicine, Seattle, WA, October 2002.
60. *Dichloroacetate (DCA) Significantly Increases the Expression of Inducible Nitric Oxide Synthase (INOS) in Human Fibroblasts of Adhesion Tissues, But Not In Normal Peritoneum.* 58th Annual Meeting of the Society for Reproductive Medicine, Seattle, WA, October 2002.
61. *Seprafilm (Modified Hyaluronic Acid Carboxymethylcellulose) Acts as a Mechanical Barrier.* 49th Scientific Meeting of the Society for Gynecologic Investigation, Los Angeles, CA, March 2002.
62. *Inhibition of Cyclooxygenase-2 in Human Adhesion Fibroblasts Reduces the Expression of MMP-1 and TIMP-1.* 49th Scientific Meeting of the Society for Gynecologic Investigation, Los Angeles, CA, March 2002.
63. *Inhibition of Cyclooxygenase-2 in Human Adhesion Fibroblasts Reduces the Expression of Transforming Growth Factor Beta-1.* 49th Scientific Meeting of the Society for Gynecologic Investigation, Los Angeles, CA, March 2002.
64. *Adhesion Phenotype: Cyclooxygenase-2 is Expressed in Fibroblasts Isolated From Adhesions, But Not From Normal Peritoneal Tissues.* 49th Scientific Meeting of the Society for Gynecologic Investigation, Los Angeles, CA, March 2002.

65. *Reduction of the Expression of Type I and III Collagens in Human Adhesion Fibroblasts, But Not in Normal Peritoneal Fibroblasts by the Inhibition of Cyclooxygenase-2.* 49th Scientific Meeting of the Society for Gynecologic Investigation, Los Angeles, CA, March 2002.
66. *Dichloroacetate Significantly Reduces the Expression of Cyclooxygenase-2 in Human Fibroblasts of Adhesion Tissues.* 49th Scientific Meeting of the Society for Gynecologic Investigation, Los Angeles, CA, March 2002.
67. *Adhesion Phenotype: p53 is Expressed in Fibroblasts Isolated From Adhesions But Not From Normal Peritoneal Tissues.* 49th Scientific Meeting of the Society for Gynecologic Investigation, Los Angeles, CA, March 2002.
68. *Metabolic Regulation of Collagen I in Fibroblasts Isolated from Normal Peritoneum and Adhesions by Dichloroacetic Acid (DCA).* 28th Scientific Meeting of Gynecologic Surgeons, Dallas, TX, March 2002.
69. *An Adhesion Promoting Phenotype: Implications for Postoperative Adhesion Development.* 30th Annual Meeting American Association of Gynecologic Laparoscopists, Global Congress of Gynecologic Endoscopy, San Francisco, CA, November 2001.
70. *Differences in the Rate of Apoptosis Following Hypoxia in Human Peritoneal and Adhesion Fibroblasts.* 30th Annual Meeting American Association of Gynecologic Laparoscopists, Global Congress of Gynecologic Endoscopy, San Francisco, CA, November 2001.
71. *Modulation of the BCL-2/BAX Ratio by IFN-GAMMA and Hypoxia in Human Peritoneal and Adhesion Fibroblasts.* 57th Annual Meeting of the American Society for Reproductive Medicine, Orlando, FL, October 2001.
72. *Significance of the Effect of Hypoxia on the Rate of Apoptosis of Human Peritoneal and Adhesion Fibroblasts for Postoperative Adhesion Development.* 57th Annual Meeting of the American Society for Reproductive Medicine, Orlando, FL, October 2001.
73. *Prostaglandin E₂ Stimulates Proliferation and Reduces Apoptosis in Epithelial Ovarian Cancer Cell Lines.* 48th Annual Meeting of the Society for Gynecologic Investigation, Toronto, Canada, March 2001.
74. *Differential Modulation of BCL-2/BAX Ratio by Hypoxia in Peritoneal and Adhesion Fibroblasts Cultured from the Same Patient.* 48th Annual Meeting of the Society for Gynecologic Investigation, Toronto, Canada, March 2001.
75. *Interferon Gamma Blocks the Stimulating Effect of Hypoxia on the Expression of Type I Collagen and Fibronectin in Human Peritoneal and Adhesion Fibroblasts.* 48th Annual Meeting of the Society for Gynecologic Investigation, Toronto, Canada, March 2001.
76. *The Effect of Interferon Gamma and Hypoxia on the Expression of TGF- β Isoforms in Human Peritoneal and Adhesion Fibroblasts.* 48th Annual Meeting of the Society for Gynecologic Investigation, Toronto, Canada, March 2001.

77. *The Effect of Normoxia after Hypoxia Treatment of the Expression of Type I Collagen and TGF- β 1 in Human Peritoneal Fibroblasts: Implications for Postoperative Adhesion Development.* 48th Annual Meeting of the Society for Gynecologic Investigation, Toronto, Canada, March 2001.
78. *Modulation of the BCL-2/BAX Ratio by IFN- γ and Hypoxia in Human Peritoneal and Adhesion Fibroblasts.* 32nd Annual Meeting of the Society of Gynecologic Oncologists, Nashville, TN, February 2001.
79. *Prostaglandin in Induced COX-2 Expression and Reduced Apoptosis in Epithelial Ovarian Cancer Cells.* 32nd Annual Meeting of the Society of Gynecologic Oncologists, Nashville, TN, February 2001.
80. *The Effect of Hypoxia on the Expression of HIF-1 β , BAX, and BCL-2 in the Epithelial Ovarian Cancer Cell Line MADH2774.* 32nd Annual Meeting of the Society of Gynecologic Oncologists, Nashville, TN, February 2001.
81. *Induction of Cyclooxygenase-2 by Prostaglandin E₂ in Human Ovarian Cancer Cell Lines.* 53rd Congress of the DGGG, German Society of Gynecology and Obstetrics eV, Munich, Germany, June 2000.
82. *Type I Collagen Production by Human Peritoneal Fibroblasts in Response to Hypoxia and/or Transforming Growth Factor-Beta 1 (TGF- β 1) Treatments.* 47th Annual Meeting of the Society for Gynecologic Investigation, SGI 2000-A Millennial Milestone in Reproductive Sciences: Celebrating the Promise, Chicago, IL, March 2000.
83. *The Effect of Hypoxia on TGF- β 1 on the Expression of Cellular Fibronectin in Human Peritoneal Fibroblast Cells in Culture.* 47th Annual Meeting of the Society for Gynecologic Investigation, SGI 2000-A Millennial Milestone in Reproductive Sciences: Celebrating the Promise, Chicago, IL, March 2000.
84. *Type I Collagen Expression in Adhesion and Normal Peritoneal Tissues.* 47th Annual Meeting of the Society for Gynecologic Investigation, SGI 2000-A Millennial Milestone in Reproductive Sciences: Celebrating the Promise, Chicago, IL, March 2000.
85. *Vascular Endothelial Growth Factor (VEGF) Levels Are Elevated in Adhesion Tissue in Humans.* Annual Meeting of the American Association of Gynecologic Laparoscopists, Las Vegas, NV, November 1999.
86. *Basics of Cutaneous Wound Repair.* 4th International Conference on Postoperative Healing and Adhesions, Fort Lauderdale, FL, October 1999.
87. *The Role of Extracellular Matrix in the Formation of Postoperative Adhesion.* 4th International Conference on Postoperative Healing and Adhesions, Fort Lauderdale, FL, October 1999.
88. *The Effect of Hypoxia and TGF- β 1 on the Expression of Tissue Inhibitors of Metalloproteinases (TIMP-1) in Human Peritoneal Mesothelial Cells.* Joint meeting of the Canadian Fertility Society and the American Society for Reproductive Medicine, Toronto, Ontario, Canada, September 1999.

89. *Collagen Type I and Type III Production by Human Mesothelial Cells in Response to Hypoxia and/or TGF- β 1 Treatments.* Annual Meeting of the Society for Gynecologic Investigation, Atlanta, GA, March 1999.
90. *The Role of Apoptosis and p53 in the Pathogenesis of Keloids.* Journal of Investigative Dermatology 110: 597, 1998.
91. *Apoptosis Modulation in the Response of CTCL to PUVA.* Journal of Investigative Dermatology 110: 698, 1998.
92. *Apoptosis Dysregulation in Keloid Fibroblasts.* Journal of Investigative Dermatology 110:653, 1998.
93. *Apoptosis Regulation in the Pathogenesis of Cutaneous T-Cell Lymphoma (CTCL).* Journal of Investigative Dermatology 108:610, 1997.
94. *The Effect of PUVA Treatment on HUT78 Cell Differential Gene Expression.* Journal of Investigative Dermatology 106:906, 1996.
95. *Detection of Differentially Displayed cDNA Fragments in Normal vs Sezary Syndrome Leukocytes.* Journal of Investigative Dermatology 104: 673, 1995.
96. *Quantitative PCR Analysis of Th-1 Cytokines in HUT78 Cells after Exposure to PUVA In Vitro.* Journal of Investigative Dermatology 102: 585, 1994.
97. *Augmentation of Th-1 Cytokines in the Peripheral Blood of Sezary Syndrome Patients after Treatment with ECCP.* Journal of Investigative Dermatology 102:586, 1994.
98. *Augmentation of Th-1 Cytokines in the Peripheral Blood of SZ Patients Upon Treatment with Extracorporeal Photopheresis.* Clinical Research 41:664, 1993.
99. *Detection of T-Cell Clonality in Mycosis Fungoides by PCR-Metaphore Agarose Analysis of T-Cell Receptor- γ .* Clinical Research 41:459, 1993.
100. *Mycosis Fungoides and Psoriasis Exhibit a Th1 Type Cell Mediated Response While Sezary Syndrome Expresses A Th2 Type Response.* Clinical Research 40:730, 1992.
101. *T-Cell Receptor Gene Conservation and Rearranged Clones in Canine Mycosis Fungoides.* Clinical Research 40:505, 1992.

Poster Presentations (Referred)

1. Fletcher NM, Awonuga AO, Memaj I, Diamond MP, **Saed GM.** Interruption of MPO Binding to CD11B Selectively Kills Fibroblasts from Adhesion Tissues but not Normal Peritoneum. 73rd American Society for Reproductive Medicine Scientific Congress & Expo, San Antonio, TX, October-November 2017. Proceedings: P-264, 216, 2017.
SRS In-Training Award for Research to NM Fletcher, PhD

2. Fletcher NM, Memaj I, Abusamaan MS, Juhani A, Al-Hendy A, Diamond MP, **Saed GM**. Oxidative Stress: A Key Regulator of Leiomyoma Cell Survival. 64th Annual Scientific Meeting for the Society for Reproductive Investigation, Orlando, FL, March 2017. Fertility and Sterility 24(1) Supplement: F-124, 208A, 2017.
3. Detti L, Fletcher NM, **Saed GM**, Uhlmann RA, Christiansen ME, Williams LJ. Anti-Mullerian Hormone (AMH) Regulates BRCA1 and BRCA2 Gene Expression in an Ovarian Cortex Transplantation Model. 72nd Annual Meeting of the American Society for Reproductive Medicine, Salt Lake City, UT, October 2016. Fertility and Sterility 106(3) Supplement: P-037, e120, 2016.
4. Fletcher NM, Belotte J, Saed MG, Abusamaan MS, Diamond MP, **Saed GM**. Chemotherapy Induces a Genotype Switch in Key Antioxidant Enzymes: A Potential Mechanism of Chemoresistance in Epithelial Ovarian Cancer Cells. 63rd Annual Meeting of the Society for Reproductive Investigation, Montreal, Quebec, Canada, March 2016. Reproductive Sciences 23(1) Supplement: F-248, 262-263A, 2016.
5. Detti L, Fletcher NM, Uhlmann RA, Belotte J, Williams LJ, **Saed GM**. Exposure to Recombinant Anti-Mullerian Hormone (AMH) Downregulates Ovarian Follicle Cells' Stemness Potential in Fresh and Vitrified/Thaw Ovarian Cortex. 63rd Annual Meeting of the Society for Reproductive Investigation, Montreal, Quebec, Canada, March 16-19, 2016. Reproductive Sciences 23(1) Supplement: T-257, 180A, 2016.
6. Nusrat O, Belotte J, Fletcher NM, Saed MG, Diamond MP, **Saed GM**. Chemoresistant Ovarian Cancer Cells Manifest Lower Vascular Endothelial Growth Factor and Hypoxia Inducible Factor-1 α : A Potential Survival Mechanism. 63rd Annual Meeting of the Society for Reproductive Investigation, Montreal, Quebec, Canada, March 16-19, 2016. Reproductive Sciences 23(1) Supplement: T-250, 178A, 2016.
7. Fletcher NM, Neubauer BR, Saed MG, Abu-Soud HM, **Saed GM**. 2,4-Dinitrophenol Induced Cell Death of Ovarian Cancer Stem Cells. 62nd Annual Meeting of the Society for Reproductive Investigation, San Francisco, CA, March 2015. Reproductive Sciences 22(1) Supplement: S-003, 299A, 2015.
8. Fletcher NM, Neubauer BR, Saed MG, Diamond MP, Abu-Soud HM, **Saed GM**. Postoperative Adhesion Development is Controlled by Mechanisms Emanating from a Hypoxia-Induced Genotype Switch in Nicotinamide Adenine Dinucleotide Phosphate Oxidase Through the Up-Regulation of Cytidine Deaminase. 62nd Annual Meeting of the Society for Reproductive Investigation, San Francisco, CA, March 2015. Reproductive Sciences 22(1) Supplement: F-042, 218A, 2015.
9. Detti L, Williams LJ, Fletcher NM, **Saed GM**. Anti-Müllerian Hormone (AMH) May Inhibit Oocyte Maturation and Follicular Vascularization in Human Ovarian Cortex. Proceedings of the 71st Annual Meeting of the American Society for Reproductive Medicine, Baltimore, MD, October 2015. Fertility and Sterility 104(3) Supplement: P91, e136, 2015.

10. Fletcher NM, Saed MG, Neubauer BR, Abusamaan MS, Al-Hendy A, Diamond MP, Berman JM, **Saed GM**. Uterine Fibroids Are Characterized by An Altered Redox Balance, Favoring A Pro-Oxidant State. 71st Annual Meeting of the American Society for Reproductive Medicine, Baltimore, MD, October 2015. Fertility and Sterility 104(3) Supplement: P-115, e145, 2015.
11. Fletcher NM, Saed MG, Neubauer BR, Abu-Soud HM, Awonuga A, Diamond MP, **Saed GM**. Shifting Anaerobic to Aerobic Metabolism Stimulates Apoptosis in Adhesion Fibroblasts Through the Modulation of the Cellular Redox Homeostasis. 71st Annual Meeting of the American Society for Reproductive Medicine, Baltimore, MD, October 2015. Fertility and Sterility 104(3) Supplement: P-215, e179, 2015.
12. Abusamaan MS, Fletcher NM, Saed MG, Al-Hendy A, Diamond MP, Berman JM, **Saed GM**. Myeloperoxidase Serves As A Redox Switch That Regulates Apoptosis In Human Leiomyomas. 71st Annual Meeting of the American Society for Reproductive Medicine, Baltimore, MD, October 2015. Fertility and Sterility 104(3) Supplement: P-113, e145, 2015.
13. Fletcher NM, Detti L, Neubauer BR, Saed MG, Diamond MP, Abuzeid MI, **Saed GM**. Altered Redox State in the Endometrium of Patients Undergoing Ovarian Stimulation for Assisted Reproduction Technology. Proceedings of the 70th Annual Meeting of the American Society for Reproductive Medicine, Honolulu, HI, October 2014. Fertility and Sterility 102(35) Supplement: P-426, e279, 2014.
14. Belotte J, Fletcher NM, Diamond MP, **Saed GM**. Sox2 Gene Amplification Impacts Survival in Serous Epithelial Ovarian Cancer. 61st Annual Meeting of the Society for Investigation, Florence, Italy, March 2014. Reproductive Sciences 21(3) Supplement: T-219, 204A, 2014.
15. **Saed GM**, Fletcher NM, Belotte J, Levin NK, Simon MS, Abu-Soud HM, Tainsky MA, Diamond. SNPs in Key Oxidants and Antioxidants Are Associated with Increased Risk and Serve as Potential Targets for Ovarian Cancer. 61st Annual Meeting of the Society for Gynecologic Investigation, Florence, Italy, March 2014. Reproductive Sciences 21(3) Supplement: T-249, 213A, 2014.
16. Diamond MP, Fletcher NM, Saed MG, Abu-Soud HM, Al-Hendy A, **Saed GM**. Fibroids Manifest Oxidative Stress As Compared to Normal Myometrium. 42nd Annual AAGL Global Congress of Minimally Invasive Gynecology, Washington, DC, November 2013. The Journal of Minimally Invasive Gynecology 20(6) Suppl: S19, 2013.
17. Diamond MP, Fletcher NM, Abuanzeh S, Saed MG, **Saed GM**. Creation and Persistence of the Adhesion Phenotype: The Role of NOXs in Creating Oxidative Stress. 42nd Annual AAGL Global Congress of Minimally Invasive Gynecology, Washington, DC, November 2013.
18. Fletcher NM, Saed MG, Abu-Soud HM, Al-Hendy A, Diamond MP, **Saed GM**. Distinct Oxidative Stress Profile in Uterine Fibroids Versus Adjacent Myometrium. Conjoint Meeting of the International Federation of Fertility Societies and the 69th American Society for Reproductive Medicine, Boston, MA, October 2013. Fertility and Sterility 100(3) Suppl: S34, 2013.

19. Fletcher NM, Abuanzeh S, Saed MG, Abu-Soud HM, Diamond MP, **Saed GM**. Postoperative Adhesion is Characterized by a Unique Oxidative Stress Profile Which is Responsible for Creation and Persistence of the Adhesion Phenotype. Conjoint Meeting of the International Federation of Fertility Societies and the 69th American Society for Reproductive Medicine, Boston, MA, October 2013. Fertility and Sterility 100(3) Suppl: S31, 2013.
20. Thakur M, Imudia AN, Shavell VI, Singh M, Diamond MP, Awonuga AO, **Saed GM**. Should Body Mass Index Influence the Dose of hCG for Ovulation Induction After Superovulation in IVF/ICSI cycles? 68th Annual Meeting of the American Society for Reproductive Medicine, San Diego, CA, October 2012. Fertility and Sterility 98(3) Suppl: P-542, S271, 2012.
21. Fletcher NM, Al-Hendy A, Diamond M, **Saed GM**. Uterine Fibroids Are Characterized by an Impaired Antioxidant Cellular System: Potential Role of Hypoxia in the Pathophysiology of Fibroids. 68th Annual Meeting of the American Society for Reproductive Medicine, San Diego, CA, October 2012. Fertility and Sterility 98(3) Suppl: P-403, S231, 2012.
22. Detti L, Uhlmann RA, Fletcher NM, Diamond MP, **Saed GM**. Endometrial Thyroid and Vitamin D Signaling Pathways during Ovarian Stimulation for Assisted Reproductive Technology (ART). 68th Annual Meeting of the American Society for Reproductive Medicine, San Diego, CA, October 2012. Fertility and Sterility 98(3) Suppl: P-384, S225, 2012.
23. Fletcher NM, Belotte J, Diamond MP, **Saed GM**. Dichloroacetate Increases Sensitivity to Chemotherapy Treatment of Epithelial Ovarian Cancer Cells. 59th Annual Meeting of the Society for Gynecologic Investigation, San Diego, CA, March 2012. Reproductive Sciences 19(3) Suppl: S-065, 354A, 2012.
24. Banerjee J, Maitra D, Shaeib F, **Saed GM**, Diamond MP, Abu-Soud HM. Melatonin Prevents Hypochlorous Acid Induced Alteration of the Metaphase-II Mouse Oocyte Microtubule and Chromosomal Structure. 59th Annual Meeting of the Society for Gynecologic Investigation, San Diego, CA, March 2012. Reproductive Sciences 19(3) Suppl: E-212, 289A, 2012.
25. **Saed GM**, Fletcher NM, Ruden DM, Abu-Soud HM, Diamond MP. Epigenetics: New Insights into Postoperative Adhesion Development. 59th Annual Meeting of the Society for Gynecologic Investigation, San Diego, CA, March 2012.
26. Nair S, **Saed GM**, Atta HM, Diamond M, Al-Hendy A. Gene Therapy of Abdominal/Pelvic Post-Operative Adhesions: Targeting Adenovirus towards Human Peritoneal Adhesion Cells. 59th Annual Meeting of the Society for Gynecologic Investigation, San Diego, CA, March 2012. Reproductive Sciences 19(3) Suppl: T-066, 141A, 2012
27. Banerjee J, Maitra D, Shaeib F, **Saed GM**, Diamond MP, Abu-Soud H. Role of Melatonin in Preventing Hypochlorous Acid Induced Alterations in Microtubule and Chromosomal Structure in Metaphase-II Mouse Oocytes *In Vitro*. 67th Annual Meeting of the American Society for Reproductive Medicine, Orlando, FL, October 2011. Fertility and Sterility (Suppl 1): P-450, 2011.

28. Abu-Farsakh SM, Abu-Farsakh HM, Fletcher NM, **Saed GM**, Diamond MP. Histopathologic Analysis in Testicular Azoospermia. 67th Annual Meeting of the American Society for Reproductive Medicine, Orlando, FL, October 2011. Fertility and Sterility (Suppl 1): P-183, 2011.
29. Shavell VI, Fletcher NM, Jiang ZL, **Saed GM**, Diamond MP. Uncoupling Oxidative Phosphorylation with 2,4-Dinitrophenol Promotes Development of the Adhesion Phenotype. 67th Annual Meeting of the American Society for Reproductive Medicine, Orlando, FL, October 2011. Fertility and Sterility (Suppl 1): P-131, 2011.
30. Nair S, **Saed G**, Nwaobasi N, Atta H, Al-Hendy A. Towards Gene Therapy of Pelvic Post-Operative Adhesions: Targeting Adenovirus Towards Human Adhesion Cells. 67th Annual Meeting of the American Society for Reproductive Medicine, Orlando, FL, October 2011. Fertility and Sterility (Suppl 1): P-111, 2011.
31. Detti L, **Saed GM**, Fletcher NM, Kruger ML, Brossoit B, Diamond MP. Endometrial Morphology and Modulation of Hormone Receptors during Ovarian Stimulation for Assisted Reproductive Technology Cycles. 66th Annual Meeting of the American Society for Reproductive Medicine, Denver, CO, October 2010. Fertility and Sterility 94(4) Suppl 1: S213-S214, 2010.
32. Fletcher NM, Jiang ZI, Almahmoud H, Diamond MP, **Saed GM**. Human Adhesion Fibroblasts Are Under Constant intrinsic oxidative stress as characterized by higher baseline NADPH oxidase and hypoxia inducible factor- 1 α and lower baseline superoxide dismutase. 66th Annual Meeting of the American Society for Reproductive Medicine, Denver, CO, October 2010. Fertility and Sterility 94(4) Suppl 1: S208, 2010.
33. White J, Jiang Z, Diamond M, **Saed G**. The role of macrophages in the development of the adhesion phenotype. Proceedings of the 66th Annual Meeting of the American Society for Reproductive Medicine, Denver, CO, October 2010. Fertility and Sterility 94(4) Suppl 1: S202, 2010.
34. Huang K, **Saed GM**, Crispino J, Song J, Choi SD, Diamond M, Naftolin F. Membrane-actin cytoskeleton linking protein expression by human post-operative adhesions and fibroblasts. 57th Annual Meeting of the Society for Gynecologic Investigation, Orlando, FL, March 2010. Reproductive Sciences 17(3) Suppl: P655, 253A, 2010.
35. **Saed GM**, Jiang ZL, Fletcher NM, Al Arab A, Abu-Soud HM, Munkarah AM, Diamond MP. Dichloroacetate induces apoptosis of epithelial ovarian cancer cells through the inhibition of oxidative stress enzymes. Proceedings of the 57th Annual Meeting of the Society for Gynecologic Investigation, Orlando, FL, March 2010. Reproductive Sciences 17(3) Suppl: P171, 113A, 2010.
36. **Saed GM**, Jiang ZL, Fletcher NM, Ali-Fehmi R, Diamond MP, Abu-Soud HM, Munkarah AR. Inhibition of NADPH oxidative reductase promotes apoptosis in epithelial ovarian cancer cells. Proceedings of the 57th Annual Meeting of the Society for Gynecologic Investigation, Orlando, FL, March 2010. Reproductive Sciences 17(3) Suppl: P170, 113A, March 2010.

37. Meng Q, Sun W, Jiang ZL, Fletcher NM, **Saed GM**, Diamond MP. Endometriotic implants resemble ovarian cancer in their inflammatory cytokines and hormone receptors expression: potential transformation into ovarian cancer. Proceedings of the 57th Annual Meeting of the Society for Gynecologic Investigation, Orlando, FL, March 2010. Reproductive Sciences 17(3) Suppl: P97, 93A, 2010.
38. **Saed GM**, Jiang ZL, Fletcher NM, Abu-Soud HM, Diamond MP. Polychlorinated biphenyl congeners induce the adhesion phenotype by reducing superoxide dismutase levels. 65th Annual Meeting of the American Society for Reproductive Medicine, Atlanta, GA, October 2009. Fertility and Sterility 90(Suppl.1): P179, October 2009.
39. **Saed GM**, Hall DT, Omar MW, Shavell VI, Fletcher NM, Diamond MP. Regulation of metabolic activity of peritoneal fibroblasts by dichloroacetate provides a potential target for interventions to reduce postoperative adhesions. 65th Annual Meeting of the American Society for Reproductive Medicine, Atlanta, GA, October 2009. Fertility and Sterility 90(Suppl. 1): P127, October 2009.
40. White J, Jiang Z, Diamond M, **Saed G**. Hypoxia induces transforming growth factor beta 1 (TGF β 1) in human macrophages through a hypoxia inducible factor 1 α (HIF-1 α) – dependent mechanism. 65th Annual Meeting of the American Society for Reproductive Medicine, Atlanta, GA, October 2009. Fertility and Sterility 90(Suppl. 1): P126, October 2009.
41. **Saed GM**, Fletcher NM, Jiang ZL, Abu-Soud HM, Diamond MP. Sensitivity of human normal peritoneal and adhesion fibroblasts to hypoxia-induced lipid peroxidation depends on the bioavailability of hydrogen peroxide. 56th Annual Scientific Meeting of the Society for Gynecologic Investigation, Glasgow, Scotland, United Kingdom, March 2009. Reproductive Sciences 16(3) Suppl: P1004, 359A, 2009.
42. Abu-Soud HM, Jiang ZL, Fletcher NM, Diamond MP, **Saed GM**. Exposure to polychlorinated biphenyls enhances lipid peroxidation in human normal peritoneal and adhesion fibroblasts: a potential role for MPO. 56th Annual Scientific Meeting of the Society for Gynecologic Investigation, Glasgow, Scotland, United Kingdom, March 2009. Reproductive Sciences 16(3) Suppl: P985, 354A, 2009.
43. Jiang ZL, Fletcher NM, Malone JM Jr, Ali R, Munkarah AR, Diamond MP, Abu-Soud HM, **Saed GM**. NADPH oxidase inhibition attenuates oxidative stress in epithelial ovarian cancer. 56th Annual Scientific Meeting of the Society for Gynecologic Investigation, Glasgow, Scotland, United Kingdom, March 2009. Reproductive Sciences 16(3) Suppl: P291, 153A, 2009.
44. Detti L, **Saed GM**, Jiang Z, Fletcher NM, Diamond MP. Impact of high serum estradiol on endometrial estrogen and progesterone receptor expression during ovarian stimulation for IVF/ICSI cycles. 64th Annual Meeting of the American Society for Reproductive Medicine, San Francisco, CA, November 2008. Fertility and Sterility 90(Suppl. 1): P157, S162, 2008.
45. **Saed GM**, Fletcher NM, Jiang ZL, Abu-Soud HM, Diamond MP. The induction of fibrosis by organochlorines through a nitric oxide synthase dependent mechanism. 64th Annual Meeting of the American Society for Reproductive Medicine, San Francisco, CA, November 2008.

46. Dbouk T, Fletcher NM, Jiang ZL, Abu-Soud HM, Diamond MP, **Saed GM**. Lycopene a powerful antioxidant with remarkable anti-adhesion effects. 64th Annual Meeting of the American Society for Reproductive Medicine, San Francisco, CA, November 2008. Fertility and Sterility 90(Suppl. 1): P-122, S150, 2008.
47. **Saed GM**, Jiang ZL, Fletcher NM, Abu-Soud HM, Diamond MP. Hypoxia induces the adhesion phenotype by reducing superoxide dismutase levels. 55th Annual Meeting of the Society for Gynecologic Investigation, San Diego, CA, March 2008. Reproductive Sciences 15(2) Suppl.: P900, 313A, 2008.
48. Alpay Z, Savasan S, Buck S, Kiang ZL, Ravindranath Y, Diamond MP, **Saed GM**. Role of natural killer lymphocyte NKG2D receptor pathway in adhesion development. 55th Annual Meeting of the Society for Gynecologic Investigation, San Diego, CA, March 2008. Reproductive Sciences 15(2) Suppl.: P317, 150A, 2008.
49. Elhammady E, Freeman ML, **Saed GM**, Diamond MP. In vivo expression of type I and III collagens in injured peritoneum that healed with adhesions and without adhesions. 63rd Annual Meeting of the American Society for Reproductive Medicine, Washington, DC, October 2007. Fertility and Sterility 88(Suppl. 1): P-252, S192, 2007.
50. **Saed GM**, Jiang ZL, Fletcher NM, Galijasevic S, Diamond MP, Abu-Soud HM. S-nitrosylation of Caspase-3 is the mechanism by which adhesion fibroblasts manifest lower apoptosis. 63rd Annual Meeting of the American Society for Reproductive Medicine, Washington, DC, October 2007. Fertility and Sterility 88(Suppl. 1): P-302, S209, 2007.
51. **Saed GM**, Jiang ZL, Diamond MP, Abu-Soud HM. Role of superoxide and nitric oxide in the development of postoperative adhesions. 54th Annual Meeting of the Society for Gynecologic Investigation, Reno, NV, March 2007. Reproductive Sciences 14(Suppl. 1): P781, 277A, 2007.
52. **Saed GM**, Jiang ZL, Diamond MP, Abu-Soud HM. Peroxynitrite plays a critical role in caspase-3 mediated apoptosis of normal peritoneal fibroblasts. 54th Annual Meeting of the Society for Gynecologic Investigation, Reno, NV, March 2007. Reproductive Sciences 14(Suppl. 1): P483, 193A, 2007.
53. **Saed GM**, Wirth JJ, Diamond MP. Polychlorinated biphenyl congeners enhancement of type I collagen expression. 62nd Annual Meeting of the American Society for Reproductive Medicine, New Orleans, LA, October 2006. Fertility and Sterility 86(Suppl. 2): P-401, S284, 2006.
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15. Awonuga AO, Fletcher NM, Belotte J, Diamond MP, **Saed GM**. The in-vivo effects of superoxide dismutase on the incidence and severity of postoperative adhesion development. 4th Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2014. Program and Abstracts: #P-02, pg. 15, 2014.
16. **Saed GM**. The role of oxidative stress in the pathogenesis of pro-fibrotic gynecologic disorders. 4th Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2014. Program and Abstracts: #O-13, pg. 13, 2014.
17. Najafi T, Goud AP, Goud PT, **Saed GM**, Gonik B, Abu-Soud HM. Release of substrates, cofactors, and products of nitric oxide synthase are altered during oocyte aging. 4th Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2014. Program and Abstracts: #O-12, pg. 12, 2014.
18. Shaeib F, Khan SN, Ali I, Dai J, Drewlo S, **Saed GM**, Abu-Soud HM. The impact of myeloperoxidase on metaphase II mouse oocyte quality. 4th Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2014. Program and Abstracts: #O-11, pg. 11, 2014.

19. Fletcher NM, **Saed GM**. Differential expression of glutathione peroxidase and glutathione reductase in chemoresistant epithelial ovarian cancer cells. 4th Annual Research Symposium of the Michigan Alliance for Reproductive Technologies and Science (MARTS), University of Michigan, Ann Arbor, MI, May 2013.
20. Shaeib F, Banerjee J, Thakur M, Saed MG, Diamond MP, **Saed GM**, Abu-Soud HM. Confocal 3-dimensional reconstruction can serve as a useful tool to quantify oxidative stress induced oocyte spindle damage. 3rd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 15, 2013. Program and Abstracts: #35, 2013.
21. Fletcher NM, **Saed GM**. Differential expression of glutathione peroxidase and glutathione reductase in chemoresistant epithelial ovarian cancer cells. 3rd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2013: Program and Abstracts: #26, 2013.
22. **Saed GM**. Investigation of the role of oxidative stress in the pathophysiology of gynecologic fibrotic disorders including postoperative adhesions, fibroids, and endometriosis as well as ovarian cancer. 3rd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2013. Program and Abstracts: #20, 2013.
23. Belotte J, Mitchell A, Belotte J, **Saed GM**. Sox2 gene copy number alteration (CAN) significantly impact overall survival (OS) in serous epithelial ovarian cancer. 3rd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2013. Program and Abstracts: #6, 2013.
24. Belotte J, Fletcher NM, Abuanzeh S, Levin NK, Simon NS, Diamond MP, Abu-Soud HM, Tainsky MA, **Saed GM**. A novel association between a catalase single nucleotide polymorphism and increased risk of ovarian cancer. 3rd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2013. Program and Abstracts: #4, 2013.
25. Awonuga AO, King NM, Belotte J, Abuanzeh S, Diamond MP, **Saed GM**. The in vitro effects of superoxide dismutase on the incidence and severity of post-operative adhesion development after cecal abrasion. 3rd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2013. Program and Abstracts: #3, 2013.
26. Shavell VI, Fletcher NM, Abu-Soud HM, Diamond MP, **Saed GM**, Detti L. Superoxide dismutase levels are elevated in the peri-implantation endometrium in women undergoing ovarian stimulation. 3rd Annual Michigan Alliance for Reproductive Technologies and Science Research Symposium, Wayne State University School of Medicine, Detroit, MI, May 2012. Proceedings and Abstracts: #15, 2012.

27. Maitra D, Abdulhamid I, **Saed GM**, Diamond MP, Pennathur S, Abu-Soud HM. Fluorescent heme degradation products in Sick cell disease: role of hypochlorous acid in hemoglobin destruction. 3rd Annual Michigan Alliance for Reproductive Technologies and Science Research Symposium, Wayne State University School of Medicine, Detroit, MI, May 2012. Proceedings and Abstracts: #12, 2012.
28. Maitra D, Abdulridha RM, Byun J, Souza CEA, Banerjee J, Andreana PR, Diamond MP, **Saed GM**, Pennathur S, Abu-Soud. The reaction of HOCl and cyanocobalamin: corrin destruction and the liberation of cyanogens chloride. 3rd Annual Michigan Alliance for Reproductive Technologies and Science Research Symposium, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #11, 2012.
29. Fletcher NM, Belotte J, Diamond MP, **Saed GM**. Dichloroacetate increases sensitivity to chemotherapy treatment of epithelial ovarian cancer cells. 3rd Annual Michigan Alliance for Reproductive Technologies and Science Research Symposium, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #8, 2012.
30. Belotte J, Fletcher NM, Diamond MP, **Saed GM**. The role of oxidative stress in the development of cisplatin resistance in epithelial ovarian cancer. 3rd Annual Michigan Alliance for Reproductive Technologies and Science Research Symposium, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #6, 2012.
31. Banerjee J, Maitra D, Shaeib F, **Saed GM**, Diamond MP, Abu-Soud HM. Melatonin prevents hypochlorous acid induced alteration of the metaphase-II mouse oocyte microtubule and chromosomal structure. 3rd Annual Michigan Alliance for Reproductive Technologies and Science Research Symposium, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #5, 2012.
32. Maitra D, Shaeib F, Abdulridha RM, Souza CEA, **Saed GM**, Abu-Soud HM. Modulation of myeloperoxidase activity by self-generated hypochlorous acid. 3rd Annual Michigan Alliance for Reproductive Technologies and Science Research Symposium, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #1, 2012.
33. Maitra D, Shaeib F, Abdulridha RM, Souza CEA, **Saed GM**, Abu-Soud HM. Modulation of myeloperoxidase activity by self-generated hypochlorous acid. 2nd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #32, 2012.
34. Fletcher NM, Belotte J, Diamond MP, **Saed GM**. Dichloroacetate increases sensitivity to chemotherapy treatment of epithelial ovarian cancer cells. 2nd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #31, 2012.

35. Belotte J, Fletcher NM, Diamond MP, **Saed GM**. The role of oxidative stress in the development of cisplatin resistance in epithelial ovarian cancer. 2nd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #29, 2012.
36. Banerjee J, Maitra D, Shaeib F, **Saed GM**, Diamond MP, Abu-Soud HM. Melatonin prevents hypochlorous acid induced alteration of the metaphase-II mouse oocyte microtubule and chromosomal structure. 2nd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #25, 2012.
37. Maitra D, Abdulridha RM, Byun J, Souza CEA, Banerjee J, Andreana PR, Diamond MP, **Saed GM**, Pennathur S, Abu-Soud HM. The reaction of HoCl and cyanocobalamin: corrin destruction and the liberation of cyanogens chloride. 2nd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #23, 2012.
38. Shavell VI, Fletcher NM, Abu-Soud HM, Diamond MP, **Saed GM**, Detti LL. Superoxide dismutase levels are elevated in the peri-implantation endometrium in women undergoing ovarian stimulation. 2nd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2012. Programs and Abstracts: #17, 2012.
39. Maitra D, Abdulhamid I, **Saed GM**, Diamond MP, Pennathur S, Abu-Soud HM. Fluorescent heme degradation products in sickle cell disease: role of hypochlorous acid in hemoglobin destruction. 2nd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2012. Programs and Abstracts: #16, 2012.
40. **Saed GM**. Investigation of the role of oxidative stress in the pathophysiology of gynecologic fibrotic disorders including postoperative adhesions, fibroids, and endometriosis as well as ovarian cancer. 2nd Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2012. Program and Abstracts: #9, 2012.
41. Shavell VI, Fletcher NM, Jiang ZL, **Saed GM**, Diamond MP. Coupling oxidative phosphorylation with 2,4-dinitrophenol promotes development of the adhesion phenotype. 1st Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Southfield, MI, May 2011. Program and Abstracts: #26, 2011.

42. **Saed GM.** The role of oxidative stress in the pathophysiology of gynecologic fibrotic disorders including postoperative adhesions, fibroids, and endometriosis, as well as ovarian cancer. 1st Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Southfield, MI, May 2011. Program and Abstracts: #24, 2011.
43. Maitra D, Shaeib F, Diamond MP, **Saed GM**, Abu-Soud HM. Melatonin can attenuate HOCl mediated hemolysis, free iron release and heme degradation from hemoglobin. 1st Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Southfield, MI, May 2011. Program and Abstracts: #19, 2011.
44. Maitra D, Byun J, Andreana PR, Abdulhamid I, Diamond MP, **Saed GM**, Pennathur S, Abu-Soud HM. Reaction of hemoglobin with HOCl: possible link between free iron accumulation and oxidative stress. 1st Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Southfield, MI, May 2011. Program and Abstracts: #18, 2011.
45. Fletcher NM, Jiang ZL, Levin NK, Abu-Soud HM, Munkarah AR, Tainsky MA, Diamond MP, **Saed GM.** Positive correlation between serum myeloperoxidase and free iron levels with stage of ovarian cancer: potential biomarkers for early detection and prognosis of ovarian cancer. 1st Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Southfield, MI, May 2011. Program and Abstracts: #13, 2011.
46. Banerjee J, Maitra D, Shaeib F, **Saed GM**, Diamond MP, Abu-Soud HM. Role of melatonin in preventing hypochlorous acid induced alterations in microtubule and chromosomal structure in metaphase-II mouse oocytes *in vitro*. 1st Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Southfield, MI, May 2011. Program and Abstracts: #7, 2011.
47. Diamond MP, **Saed GM.** Reduction of postoperative adhesions. Catalyzing Collaboration between Industry and Academic in the Life Sciences – Women’s Health Medicine: Part I, Therapeutic Strategies Meeting, Illinois Science and Technology Park, Skokie, IL, June 2007. Proceedings 2007.

Invited Lectures/Presentations

International/National

1. *Targeting Integrin $\alpha V/\beta 1$ Receptor Manifests Intriguing Anti-Tumor Effects in Sensitive and Chemoresistant Ovarian Cancer Cells: Potential Therapeutic Target.* 64th Annual Scientific Meeting of the Society for Reproductive Investigation, Orlando, FL, March 2017.
2. *The Role of Oxidative Stress in the Pathogenesis of Ovarian Cancer.* University of Jordan, Amman, Jordan, July 2017.
3. *Novel Innovative Targets for Ovarian Cancer Therapy.* King Hussein Cancer Center, Amman, Jordan, July 2017.
4. *The Role of Oxidative Stress in the Pathogenesis of Ovarian Cancer.* King Hussein Cancer Center, Amman, Jordan, November 2016.
5. *The Role of Oxidative Stress in the Pathogenesis of Ovarian Cancer.* University of Jordan, Amman, Jordan, November 2016.
6. *New Insights for Ovarian Cancer Screening.* 4th International Conference of the Jordanian Society of Pathology and Laboratory Medicine. In collaboration with the Arabic Division of the International Academy of Pathology, Amman, Jordan, April 2011.
7. *Updates in Oxidative Stress and Ovarian Cancer.* Modern Technology Application in Pathology Conference, Amman, Jordan, July 22 – August 1, 2010.
8. *The Role of p53 in the Pathogenesis of Keloids.* International Meeting on Mechanisms Involved in Tissue Repair and Fibrosis: Role of the Microfibroblast (Differentiation and Apoptosis), Lyon, France, December 1997.

Local/Regional

1. *The Role of Oxidative Stress in the Pathogenesis of Ovarian Cancer.* Joint Annual Reproductive Sciences Retreat, Departments of Obstetrics and Gynecology, Wayne State University School of Medicine and The University of Toronto; and Annual Michigan Alliance for Reproductive Technologies and Sciences (MARTS) Meeting at Wayne State University, Detroit, MI, October 2017. Retreat
2. *Invited Guest Speaker.* Tumor Microenvironment Section, Karmanos Cancer Center, Detroit Medical Center/Wayne State University School of Medicine, Detroit, MI, June 2016.
3. *Molecular Biological Procedures.* C.S. Mott Center for Human Growth and Development, Division of Reproductive Endocrinology and Infertility Laboratory Techniques Summer Course, Wayne State University School of Medicine, Detroit, MI, September 2015.

4. *New Insights into Pathogenesis of Ovarian Cancer.* The C.S. Mott Center Summer Reproductive Sciences Technology Course, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, July 2014.
5. *The Role of Oxidative Stress in the Pathogenesis of Pro-Fibrotic Gynecologic Disorders.* 4th Annual Scientific Retreat, The C.S Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2014.
6. *Release of Substrates, Cofactors, and Products of Nitric Oxide Synthase Are Altered during Oocyte Aging.* 4th Annual Scientific Retreat, The C.S Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2014.
7. *The Impact of Myeloperoxidase on Metaphase II Mouse Oocyte Quality.* 4th Annual Scientific Retreat, The C.S Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, May 2014. **First Prize Award**
8. *Differential Expression of Glutathione Peroxidase and Glutathione Reductase in Chemoresistant Epithelial Ovarian Cancer Cells.* The Michigan Alliance for Reproductive Technologies and Science (MARTS), Fourth Annual Research Symposium, University of Michigan, Ann Arbor, MI, May 2013.
9. *The Role of Oxidative Stress in the Pathophysiology of Gynecologic Fibrotic Disorders: Postoperative Adhesions, Fibroids, Endometriosis, and Ovarian Cancer.* 1st Annual Scientific Retreat of The C.S. Mott Center for Human Growth and Development, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Southfield, MI, May 2011.
10. *New Insights in Ovarian Cancer Screening.* Department of Obstetrics and Gynecology Wayne Day: New Frontiers in the Treatment of Gynecologic Cancer, Wayne State University School of Medicine, Detroit, MI, December 2010.
11. *Molecular Characterization of Adhesion and Peritoneal Fibroblasts.* Adhesion Mini Symposium, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, March 2001.
12. *Multiplex RT/PCR Technique, Concept and Application.* Center for Biomedical Research, College of Art and Sciences, Oakland University, Rochester, MI, May 1999.
13. *Techniques for Characterizing and Manipulating DNA from the Basis of Much of Modern Biomedical Research.* Department of Chemistry, Oakland University, Rochester, MI, January 1999.
14. *Bcl-2/Bax Ratio as a Measure of the Rate of Apoptosis in Keloid Fibroblasts.* Oxford Biomedical Research Inc., Oxford, MI, January 1998.
15. *PCR Techniques, Concepts and Applications.* Howard Hughes Research Program, Oakland University, Rochester, MI, May 1998.

16. *Multiplex RT/PCR Technique, Concept and Application.* Center for Biomedical Research, College of Art and Sciences, Oakland University, Rochester, MI, May 1997.
17. *Application of RT/PCR.* Department of Chemistry, Oakland University, Rochester, MI, June 1994.

Invited Seminars and Grand Rounds

1. *New Insights into the Pathogenesis of Post-Operative Adhesions Development.* Department of Obstetrics and Gynecology Grand Rounds, Georgia Regents University, Augusta, GA, January 2017.
2. *Novel Innovative Targets for Ovarian Cancer Therapy.* Cancer Center Seminar, Georgia Regents University, Augusta, GA, January 2017.
3. *The Role of Oxidative Stress in the Pathogenesis of Pro-Fibrotic Gynecologic Disorders.* Augusta Research Day, Department of Obstetrics and Gynecology Grand Rounds, Georgia Regents University, Augusta, GA, June 2013.
4. *Dichloroacetate Induces Apoptosis of Epithelial Ovarian Cancer Cells Through the Inhibition of Oxidative Stress Enzymes.* SGI-SMFM Scientific Meetings Abstract Presentations, Department of Obstetrics and Gynecology Grand Rounds, Wayne State University School of Medicine, Detroit, MI, February 2010.
5. *PCR Techniques Concepts and Clinical Applications.* Clinical Fellows Seminar, Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, Wayne State University School of Medicine, Detroit, MI, March 2000.
6. *The Role of p53 and Apoptosis in the Pathogenesis of Keloids.* Department of Obstetrics and Gynecology Grand Rounds, Wayne State University School of Medicine, Detroit, MI, July 1998.

Exhibit Y

VITAE

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EDUCATION

October 1980 to December 1983	Received Doctor of Philosophy in Materials Science and Engineering, University of Florida
June 1979 to May 1982	Received Master of Science in Materials Science and Engineering, University of Florida.
September 1972 to June 1977	Received Bachelor of Science degree; Major in Microbiology, Minor in Chemistry, University of Florida.

PROFESSIONAL WORK HISTORY

September 1987 to Present	President of MAS, LLC (previously Materials Analytical Services, Inc.) Suwanee, Georgia.
August 1987 to February 1988	President and Founder of Longo Microanalytical Services, Inc., Gainesville, Florida.
October 1983 to August 1987	President and Founder of Micro Analytical Laboratories, Inc., Gainesville, Florida.
March 1985 to December 1987	Visiting Assistant Professor; University of Florida, Department of Materials Science and Engineering.
August 1983 to March 1985	Post Doctoral Associate; University of Florida, Department of Materials Science and Engineering.



William E. Longo, Ph.D
Page 2

PATENTS

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U. S. Patent Serial No. 4871716, October 3, 1989. Goldberg, E.P., Longo, W.E., and McCluskey, R.A., "Magnetically Responsive, Hydrophilic Microspheres for Incorporation of Therapeutic Substances and Methods of Preparation Thereof."

PUBLICATIONS AND PRESENTATIONS

Egilman, D., Longo, W.E., "Egilman's Assessment Regarding Exposures of Auto Mechanics to "Amphiboles is Correct"" *Inhalation Toxicology*, 2012: 24(9); 614-618.

Rigler, M.W., Longo, W.E. & Sauerhoff, M.W.: "Exposure to Fluoropolymers and VOCs during Spray Sealant Product Use" *Inhalation Toxicology*, 23 (11): 641-657, 2011.

Ewing, W.M., Hays, S.M., Hatfield, R., Longo, W.E. & Millette, J.R. "Zonolite Attic Insulation Exposure Studies" *Int. J. Occup. Environ. Health*, Vol. 16(3), Jul/Sep, 2010.

Rigler, M.W., Longo, W.E. "Emission of Diacetyl (2,3 Butanedione) from Natural Butter, Microwave Popcorn Butter Flavor Powder, Paste, and Liquid Products", *Int. J. Occup. Environ. Health*, 16:291-302, 2010.

Rigler, M.W., Longo, W.E., "Qualitative Sulfur Gas Emission as a Specific Marker for Problematic Reactive Drywall, Proceedings of the Technical Symposium on Imported Corrosive Drywall", November 5-6, 2009, the University of Florida, Gainesville, FL.

Longo, W.E., Rigler, M.W., Russell, P.E., Vitarelli, J.P., Hoffman, E.M. & Johnson, H.M. Health Effects of Welding, "The Characterization of Welding Fume Particulates and Mn Bioavailability Studies for SMAW and FCAW Consumables" NIOSH, West Virginia, July 2005.

Harris M.D., Ewing, W.M., Longo, W.E., DePasquale, C., Mount, M.D., Hatfield, R.L. & Stapleton, R. "Manganese Exposure During Shielded Metal Arc Welding (SMAW) in an Enclosed Space" *J. Occup. & Environ. Hyg.* 2(8) 375-382, 2005.

Longo, W.E., Egeland, W.B., Hatfield, R.L., Stapleton, R., and Hubbard J., "Tremolite Analysis of Chrysotile Containing Friction and Gasket / Packing Products", ASTM Johnson Conference, Johnson Vermont, July, 2002.

William E. Longo, Ph.D
Page 3

Longo, W.E., Egeland, W.B., Hatfield, R.L., and Newton, L.R., "Fiber Release During the Removal of Asbestos-Containing Gaskets: A Work Practice Simulation" *Appl. Occup. Environ. Hyg.* 17(1) 55-62, 2002.

Hatfield, R.L., Krewer, J.A., and Longo, W.E., "A Study of the Reproducibility of the Micro-Vac Technique as a Tool for the Assessment of Surface Contamination in Buildings with Asbestos Containing Materials" (M.E. Beard and H.L. Rook) in *Advances in Environmental Measurement Methods for Asbestos*, ASTM #STP 1342,301, January, 2000.

Rigler, M.W., Freeman, G.B., Longo, W.E., Kyono, M. and Cai, M. "A New Rapid Method for Analyzing Single Particles", Proceedings of the Engineering Solutions to Indoor Air Quality Symposium for the United States Environmental Protection Agency (USEPA), July 21-26, 1997, Research Triangle Park, NC.

Longo, W.E., and Rigler, M.W., "Rapid Identification of Inorganic and Organic Particulate for Routine IAQ Assessment" Indoor Environment Meeting, April, 1996.

Longo, W.E., "Malignant Mesothelioma in Kent Cigarettes Smokers: Analysis of Asbestos Content in Filters, Cigarette Smoke and Lung Tissue" Society for Ultrastructural Pathology, March, 1996.

Longo, W.E., "The Identification of Asbestos Containing Surface Treatment Products using Standard Analytical Techniques" Florida Environmental and Asbestos Council Meeting, January, 1996.

Longo, W.E., Rigler, M.W. and Slade, J., "Crocidolite Asbestos Fibers in Smoke from Original Kent Cigarettes" *Cancer Research* 55 11, 2232, 1995.

Longo, W.E., "Occupational Exposure From In-Place Asbestos Containing Fireproofing" Environmental Information Association, April, 1995.

Keyes, D. L., Ewing, W. M., Hays, S. M., Longo, W. E. and Millette, J.R., "Baseline Studies of Asbestos Exposure During Operations and Maintenance Activities" *Appl. Occup. Environ. Hyg.* 9(11) Nov, 1994.

Goldberg, E.P., Quigg, J., Sitren, H., Hoffmann, E., Jayakrishnan, A., Longo, W. and Cantrell, J., "Microsphere Drug Carriers for Targeted Chemo Immunotherapy and for Intracellular Infections" 20th Annual Meeting of the Society for Biomaterials, 1994.

Millette, J.R., Longo, W.E. and Hubbard, J.L., "Demonstration of the Capability of Asbestos Analysis by Transmission Electron Microscopy in the 1960's" *Microscope*, 41 15, 1993.

William E. Longo, Ph.D
Page 4

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Longo, W. E. "A Standard Method for the Analysis of Asbestos in Settled Dust by TEM" Asbestos Measurement Risk Assessment and Laboratory Accreditation, ASTM Conference, July 1992. Johnson, Vermont.

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Longo, W. E. "Sampling and Analysis of Asbestos in Settled Dust" EPA/A&WMA Symposium on "Measurement of Toxic and Related Air Pollutants", May 1991. Durham, North Carolina.

Longo, W. E. "Asbestos Wipe Sampling" Industrial Hygiene Association, October, 1990. West Palm Beach, Florida.

Longo, W. E. "Standard Test Method for Asbestos Concentrations in Dust Samples" American Society of Testing Materials Subcommittee D22.05.07, manuscript in progress.

Goldberg, E. P., Yalon, M., and Longo, W. E. "Low Voltage SEM for Unique Surface Analysis of Prosthetic Devices" Materials Research Society Symposium Proceedings 110, *Biomedical Materials and Devices*, 1989.

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William E. Longo, Ph.D
Page 5

Goldberg, E. P., Yalon, M., and Longo, W. E. "Low Voltage Scanning Electron Microscopy for Improved Surface Characterization of Ocular Implants and Other Prosthetic Devices" American Chemical Society Symposium, September 1988. Los Angeles, California.

Longo, W. E. "Rinse Technique for Recovery of Air Samples for TEM Analysis" Asbestos Measurement Research and Laboratory Accreditation, ASTM Conference, July 1988. Johnson, Vermont.

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Longo, W. E. "Analysis of Asbestos by Transmission Electron Microscopy" Alabama Electron Microscopy Society 7th Annual Meeting, March 1988. Birmingham, Alabama.

Longo, W. E. "Asbestos Fiber Loss from Air Sampling Cassettes: A Study by Transmission Electron Microscopy" EPA/APCA Symposium on Measurement of Toxic and Related Air Pollutants, May 1987. Research Triangle Park, North Carolina.

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Goldberg, E. P., Iwata, H., and Longo, W. E. "Hydrophilic Albumin and Dextran Ion-Exchange Microspheres for Localized Chemotherapy" (S. Davis, L. Illium, J. McVie, and E. Tomlinson Eds) in Microspheres and Drug Therapy. Pharmaceutical Immunological and Medical Aspects, 10, 309, 1984.

Hoffmann, E. M., Longo, W. E., and Goldberg, E. P. "Macrophage Uptake of Albumin Microsphere Drug Carriers" Proceedings of the 11th International Symposium on Controlled Release of Bioactive Materials, 11, 27, 1984.

Longo, W.E., "Albumin Microspheres for the Controlled Release of Therapeutic Agents" Doctor of Philosophy Dissertation, University of Florida, 1983.

William E. Longo, Ph.D
Page 6

Longo, W. E., and Goldberg, E. P. "Novel Albumin-Polypeptide-Drug Microspheres: Synthesis and Ion Exchange Drug Release Properties" Proceedings of the 10th International Symposium on Controlled Release of Bioactive Materials, 10, 245, 1983.

Longo, W. E., Iwata, H., Lindheimer, T., and Goldberg, E. P. "Preparation and Drug Release Properties of Albumin-Polyglutamic Acid-Adriamycin Microspheres" American Chemical Society, 24, 56, 1983.

Longo, W. E., Iwata, H., Lindheimer, T., and Goldberg, E. P. "Preparation of Hydrophilic Albumin Microspheres Using Polymeric Dispersing Agents" *J. Pharm. Sci.*, 71, 1323, 1982.

Goldberg, E. P., Iwata, H., Terry, R. W., Longo, W. E., Levy, M., and Cantrell, J. L. in "Affinity Chromatography and Related Techniques" (Visser, Visser and Nivard Eds), Elsevier, Amsterdam, 375, 1982.

Longo, W. E., Iwata, H., and Goldberg, E. P. "Hydrophilic Albumin-Polyglutamic Acid-Adriamycin Microspheres for Localized Chemotherapy" 8th Annual Meeting of the Society of Biomaterials, 10, 60, 1982.

ACTIVITIES AND ORGANIZATIONS

- * Member of Environmental Protection Agency Workshop on Sampling and Analysis of Asbestos in Settled Dusts, July 1989.
- * Member of Environmental Protection Agency Peer Review Group for the Asbestos Engineering Program, 1987 to present.
- * Vice-Chairman of the National Asbestos Council Analytical Subcommittee on Transmission Electron Microscopy 1987-1988.
- * Chairman of National Asbestos Council Analytical Subcommittee on Transmission Electron Microscopy 1988-1989.
- * Member of ASTM D-22-05 Subcommittee for Indoor Air Pollution.

William E. Longo, Ph.D
Page 7

LECTURES AND COURSES INSTRUCTED

Longo, W.E. "Electron Microscopy for Industrial Hygiene Applications" American Industrial Hygiene Conference Professional Development Course, Atlanta GA, May 2004.

Longo, W. E. "Settled Dust: Asbestos and Other Particulates" Georgia Institute of Technology Seminar, August 1991.

Longo, W. E. "The Role of the Laboratory Manager, Quality Assurance Officer and the Analyst for NIST Accreditation" Georgia Institute of Technology, Transmission Electron Microscopy Asbestos Accreditation Seminar, August 1989.

Longo, W. E. 24th Annual Meeting of the Microbeam Analysis Society, "Asbestos Analysis Session" Ashville, North Carolina, July 1989 (Session Co-Chairman).

Longo, W. E. "Fundamentals of Asbestos Analysis by TEM" Institute in Materials Science State University of New York. New Paltz, New York, October 1988 (Course Director).

Longo, W. E. "TEM Imaging/Photography" Georgia Institute of Technology, Transmission Electron Microscopy Asbestos Analysis Course, June 1988.

Longo, W. E. "Laboratory Preparation of Polycarbonate Filters for TEM Analysis" Georgia Institute of Technology, Advanced Transmission Electron Microscopy Asbestos Analysis Course, February 1988.

Longo, W. E. "Transmission Electron Microscopy Laboratory Set-Up" Georgia Institute of Technology, Advanced Transmission Electron Microscopy Asbestos Analysis Course, February 1988.

Longo, W. E. "Laboratory Analysis of Asbestos" Hall-Kimbrell Seminar in Asbestos Abatement in the State of Florida, January 1988.

Longo, W. E. "Air Sample Preparation and Analysis by TEM" Georgia Institute of Technology, Clearance Testing for Asbestos: AHERA Regulations, October 1987.

Longo, W. E. "Asbestos Air Sample Analysis by Transmission Electron Microscopy" American Industrial Hygiene Conference Professional Development Course, Montreal, Canada, May 1987.

Longo, W.E. "Asbestos Air Sample Analysis by Transmission Electron Microscopy" American Industrial Hygiene Conference Professional Development Course, Dallas, TX May 1986.

William E. Longo, Ph.D
Page 8

PROFESSIONAL MEMBERSHIPS

American Industrial Hygiene Association	1985 to Present
American Society for the Testing of Materials	1987 to Present
American Society of Materials	1994 to Present
National Asbestos Council	1984 to 1993
Environmental Information Association	1993 to Present
Materials Research Society	1988 to Present
Electron Microscopy Society Association	1988 to Present
Microbeam Analysis Society	1988 to Present
New York Academy of Science	1985 to 1987 1989 to 1994
Air Pollution Control Association	1985 to 1987
National Institute of Building Sciences	1991 to Present
The Society for Ultrastructural Pathology	1996 to Present
American Society of Heating, Refrigerating and Air-Conditioning Engineers	1996 to Present
The American College of Forensic Examiners – Fellow of Forensic Engineering Technology (IN. 17825)	1999 to Present
American Conference of Governmental Industrial Hygienist (ACGIH) Associate Member	2006 to Present

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